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Reader Aids
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CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

Rules and Regulations

Federal Register
Vol. 56, No. 247
Tuesday, December 24, 1991

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 82

[Docket No. 91-132]

Exotic Newcastle Disease

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Affirmation of final rule.

SUMMARY: We are affirming without change a rule that amended the regulations concerning exotic Newcastle disease to specify our policy and procedures in cooperative programs concerning eradication of the disease from populations of birds and poultry. The rule affirmed by this action was necessary to clarify the procedures used for the control and eradication of exotic Newcastle disease.

EFFECTIVE DATE: January 23, 1992.

FOR FURTHER INFORMATION CONTACT: Dr. Maurice A. Mixson, Chief Staff Veterinarian, Emergency Programs Staff, VS, APHIS, USDA, room 810, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20872, 301-436-8073.

SUPPLEMENTARY INFORMATION:

Background

In a rule published in the Federal Register on October 9, 1980 (45 FR 67052-67055) and made effective on that date, we amended the regulations regarding exotic Newcastle disease in order to clarify procedures for the protection of poultry and bird industries against the disease with minimal disruption to owners, producers, dealers, and other aviculturists.

We solicited comments for a 60-day period, ending December 8, 1980. The comment period was then extended for 30 days until January 7, 1981 (45 FR 80813). We received a total of 15 comments, representing bird and poultry industry associations, a State department of agriculture, a humane society, and members of the general public.

One commenter supported the rule as written. The remainder of the commenters either recommended changes to the rule, or addressed issues outside the scope of the rule. The comments that requested changes to the rule or made other recommendations are discussed below.

Four commenters requested that we not take final action on the rule without first holding a public conference to discuss exotic Newcastle disease. We are making no changes based on these comments. We do not believe a public conference would elicit any information not already available. Meetings have been conducted in the past regarding APHIS's policies on exotic Newcastle disease, and our rule includes a number of provisions that are consistent with industry recommendations. However, we are fully willing to attend any national industry-sponsored meetings for further discussions of policies regarding exotic Newcastle disease.

Two commenters stated that velogenic Newcastle disease should not be classified as exotic. In our rule, we characterized as exotic only that velogenic Newcastle disease that is viscerotropic. Velogenic viscerotropic Newcastle disease is not endemic to the United States and is therefore rightfully classified as exotic.

In our rule, we included provisions for special consideration of endangered species of birds. Two commenters recommended that special consideration also be given to protecting genetic stock. Although we are making no changes based on these comments, we are in the process of carefully evaluating the issue of genetic stock and will take whatever action is appropriate.

One respondent stated that pigeons should be considered the primary source of exotic Newcastle disease. We are not aware of any studies that support this conclusion. During the 1971-1973 major outbreak of exotic Newcastle disease in California, a total of 9,446 free-flying wild birds, including pigeons, were collected and tested. It was concluded from this testing that free-flying wild birds were not a factor in the spread of exotic Newcastle disease.

A number of commenters addressed issued outside the scope of our rule, including the advisability of a total ban on the importation of birds, the feasibility of requiring the vaccination of birds prior to their importation, and elimination of indemnity payments for birds affected with exotic Newcastle disease. We are making no changes based on these comments.

The rationale we set forth for the changes made in our October 9, 1980, document was based on the exotic Newcastle disease risk at that time. That risk continues to exist today. We are therefore affirming the provisions of our October 9, 1980, rule without change.

Executive Order 12291 and Regulatory Flexibility Act

We are issuing this rule in conformance with Executive Order 12291, and we have determined that it is not a "major rule." Based on information compiled by the Department, we have determined that this rule will have an effect on the economy of less than $100 million; will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and will not cause a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States based enterprises to compete with foreign based enterprises in domestic or export markets.

The regulatory amendments being affirmed in this final rule have been in effect for a number of years and require no changes to current industry practice.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Paperwork Reduction Act

This rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*).

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

List of Subjects in 9 CFR Part 82

Animal diseases, Chlamydiosis, Exotic Newcastle disease, Ornithosis, Poultry and poultry products, Psittacosis, Salmonella, Quarantine, Transportation.

PART 82—EXOTIC NEWCASTLE DISEASE IN ALL BIRDS AND POULTRY; PSITTACOSIS AND ORNITHOSIS IN POULTRY; POULTRY DISEASE CAUSED BY SALMONELLA ENTERITIDIS

Accordingly, we are affirming, without change, the final rule amending 9 CFR Part 82 that was published at 45 FR 67052–67055 on October 9, 1980.

Authority: 21 U.S.C. 111–113, 115, 117, 120, 123–126, 134a, 134b, 134f; 7 CFR 2.17, 2.51, and 371.2(d).

Done in Washington, DC, this 19th day of December 1991.

Robert Melland,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 91–30669 Filed 12–23–91; 8:45 am]

BILLING CODE 3410–34–M

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9 CFR Part 113

[Docket No. 91–158]

Viruses, Serums, Toxins, and Analogous Products; Revision of Standard Requirements; Technical Amendment

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Technical amendment.

SUMMARY: We are making a technical amendment to the Standard Requirement for Erysipelothrix Rhusiopathiae Bacterin in the regulations that set forth standard requirements for the evaluation of veterinary biological products. This amendment removes an outdated reference to a swine potency test and removes a reserved paragraph in § 113.119. This document corrects material published in a final rule in the **Federal Register** on June 6, 1985, and in a correction to a final rule published in the **Federal Register** on July 1, 1986.

EFFECTIVE DATE: December 24, 1991.

FOR FURTHER INFORMATION CONTACT: Dr. David A. Espeseth, Deputy Director, Veterinary Biologics, BBEP, APHIS, USDA, room 838, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, (301) 436–8245.

SUPPLEMENTARY INFORMATION:

Background

The regulations at 9 CFR part 113 set forth the standard requirements to be used by licensed establishments in the evaluation of veterinary biological products. A final rule published in the **Federal Register** on June 6, 1985 (50 FR 23791, Docket No. 84–127), revised the standard requirements for eight veterinary biological products, including Erysipelothrix Rhusiopathiae Bacterin. Our intention in that final rule was to replace one mouse potency test with an improved mouse potency test, and to remove the swine potency test. (See Supplementary Information, Background, 50 FR 23792, column 2, first paragraph.) We intended to add the improved mouse test to 9 CFR 113.104(c), remove the alternate mouse test from paragraph (d), and delete the swine potency test from paragraph (e). However, neither the mouse test in paragraph (d) nor the swine test in paragraph (e) were actually removed in the rule portion of that document.

A correction was published in the **Federal Register** on July 1, 1986 (51 FR 23731, Docket No. 86–054), removing the mouse test from paragraph (d), but reserving the paragraph for later use. It did not remove the swine test from paragraph (e).

No changes were made in these paragraphs in the regulations when a final rule was published in the **Federal Register** on August 31, 1990 (55 FR 3556), redesignating § 113.104 as § 113.119.

Therefore, we are correcting § 113.119 to remove paragraphs (d) and (e).

List of Subjects in 9 CFR Part 113

Animal biologics.

Accordingly, 9 CFR part 113 is amended as follows:

PART 113—STANDARD REQUIREMENTS

1. The authority citation for part 113 is revised to read as follows:

Authority: 21 U.S.C. 151–159; 7 CFR 2.17, 2.51, and 371.2(d).

§ 113.119 [Amended]

2. In § 113.119, paragraphs (d) and (e) are removed.

Done in Washington, DC, this 19th day of December 1991.

Robert Melland,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 91–30666 Filed 12–23–91; 8:45 am]

BILLING CODE 3410–34–M

DEPARTMENT OF COMMERCE

Bureau of Export Administration

15 CFR Part 799

[Docket No. 910813–1313]

Commerce Control List; Listing of Entries in Numerical Order

AGENCY: Bureau of Export Administration, Commerce.

ACTION: Interim rule.

SUMMARY: On August 29, 1991, the Bureau of Export Administration (BXA) published an interim rule in the **Federal Register** (56 FR 42824) that established the Commerce Control List (CCL), Supplement No. 1 to § 799.1 of the Export Administration Regulations (EAR). The August 29, 1991, interim rule implemented a totally revised International Industrial List that had been developed by the Coordinating Committee for Multilateral Export Controls (COCOM). Because the revised Industrial List used a completely new method of categorizing items, BXA developed a new numbering system for both the Industrial List items and those items controlled for foreign policy, nuclear, or other reasons.

In order to assist exporters in locating the appropriate Export Control Classification Number (ECCN), BXA generally placed ECCNs that controlled items for missile technology or nuclear reasons immediately following related Industrial List items in the CCL. For example, ECCN 1A22B (a missile technology entry) was placed immediately following ECCN 1A02A (an Industrial List entry) because both entries controlled composite structures and laminates. While this approach enabled ECCNs that contained related items to be grouped together, it also had a negative effect. Many non-Industrial List items were listed out of numerical order. In the example cited above, for instance, ECCN 1A02A (the Industrial List entry) was followed by ECCN 1A22B (the missile technology entry), which was followed by ECCN 1A03A (another Industrial list entry).

In order to avoid confusion in locating entries on the CCL, this interim rule places in numerical order all of the non-Industrial List entries that were formerly out of sequence. The Export Control Classification Numbers assigned to these non-Industrial List entries have not been changed. This rearrangement of entries will not make locating related ECCNs more difficult because each Industrial List entry that was formerly followed by a related, but out of

sequence, non-Industrial List entry will now be followed by a note that will identify related non-Industrial List entries that are controlled for missile technology or nuclear reasons.

EFFECTIVE DATE: December 24, 1991.

FOR FURTHER INFORMATION CONTACT: Willard Fisher, Office of Technology and Policy Analysis, Bureau of Export Administration, Telephone: (202) 377–3856.

SUPPLEMENTARY INFORMATION:

Rulemaking Requirements

1. This rule is consistent with Executive Orders 12291 and 12661.

2. This rule involves collections of information subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). These collections have been approved by the Office of Management and Budget under control numbers 0694–0005 and 0694–0010.

3. This rule does not contain policies with Federalism implications sufficient to warrant preparation of a Federalism assessment under Executive Order 12612.

4. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by section 553 of the Administrative Procedure Act (5 U.S.C. 553) or by any other law, under sections 603(a) and 604(a) of the Regulatory Flexibility Act (5 U.S.C. 603(a) and 604(a)) no initial or final Regulatory Flexibility Analysis has to be or will be prepared.

5. The provisions of the Administrative Procedure Act, 5 U.S.C. 553, requiring notice of proposed rulemaking, the opportunity for public participation, and a delay in effective date, or inapplicable because this regulation involves a foreign and military affairs function of the United States. No other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this rule.

Therefore, this regulation is issued in interim form. Although there is no formal comment period, public comments on this regulation are welcome on a continuing basis. Comments should be submitted to Willard Fisher, Office of Technology and Policy Analysis, Bureau of Export Administration, Department of Commerce, P.O. Box 273, Washington, DC 20044.

List of Subjects in 15 CFR Part 799

Exports, Reporting and recordkeeping requirements.

Accordingly, part 799 of the Export Administration Regulations (15 CFR parts 730–799) is amended as follows:

1. The authority citation for 15 CFR part 799 is revised to read as follows:

Authority: Pub. L. 96–72, 93 Stat. 503 (50 U.S.C. app. 2401 *et seq.*), as amended; E.O. 12532 of September 9, 1985 (50 FR 36861, September 10, 1985) as affected by notice of September 4, 1986 (51 FR 31925, September 8, 1986); Pub. L. 99–440 of October 2, 1986 (22 U.S.C. 5001 *et seq.*); and E.O. 12571 of October 27, 1986 (51 FR 39505, October 29, 1986); Pub. L. 95–223, 91 Stat. 1626 (50 U.S.C. 1701 *et seq.*); Pub. L. 95–242 of March 10, 1978, 92 Stat. 141 (42 U.S.C. 2139a); E.O. 12730 of September 30, 1990 (55 FR 40373, October 2, 1990); Notice of November 14, 1991 (56 FR 58171).

PART 799—[AMENDED]

§ 799.1 [Amended]

2. Section 799.1(b)(1) is amended:

a. By revising the phrase "from 1 to 0" in the introductory text to read "from 1 to 10"; and

b. By revising the item "0—Miscellaneous" at the end of the list to read "10—Miscellaneous".

Supplement No. 1 to § 799.1 [Amended]

3. In Supplement No. 1 to § 799.1 (the Commerce Control List), Category 1 (Materials), a Related ECCNs note is added immediately following ECCN 1A02A, as follows:

Related ECCNs: See 1A22B for MT controls on "composite" structures or laminates, not controlled by 1A02A, that are usable in "missile" systems.

4. In Supplement No. 1 to § 799.1 (the Commerce Control List), the ECCNs listed below are transferred to the correct numerical order within each of the following categories:

Category 1—Materials

A. Equipment, Assemblies and Components
ECCNs: 1A22B, 1A44B, 1A45B, and 1A46B
B. Test, Inspection and Production Equipment
ECCNs: 1B21B and 1B28B
C. Materials
ECCNs: 1C21B, 1C22B, 1C27B, and 1C50E

Category 2—Materials Processing

B. Test, Inspection and Production Equipment
ECCNs: 2B41E, 2B24B, and 2B46B

Category 3—Electronics Design, Development and Production

A. Equipment, Assemblies and Components
ECCNs: 3A41E, 3A42E, and 3A43B

Category 4—Computers

A. Equipment, Assemblies and Components
ECCN: 4A21B

Category 6—Sensors

A. Equipment, Assemblies and Components
ECCNs: 6A22B, 6A42B, 6A43B, 6A28B, 6A29B, and 6A30B
D. Software
ECCNs: 6D21B and 6D22B
E. Technology
ECCNs: 6E21B and 6E22B

Category 7—Navigation and Avionics

A. Equipment, Assemblies and Components
ECCNs: 7A21B, 7A22B, 7A23B, 7A24B, 7A25B, and 7A26B
B. Test, Inspection and Production Equipment
ECCN: 7B22B
E. Technology
ECCNs: 7E21B and 7E22B

Category 9—Propulsion Systems and Transportation Equipment

A. Equipment, Assemblies and Components
ECCNs: 9A21B and 9A22B
B. Test, Inspection and Production Equipment
ECCNs: 9B21B, 9B23B, 9B24B, 9B25B, 9B26B, and 9B27B
E. Technology
ECCN: 9E21B

5. In Supplement No. 1 to § 799.1 (the Commerce Control List), Category 1 (Materials), a Related ECCNs note is added immediately following ECCN 1B01A, as follows:

Related ECCNs: See 1B21B for MT controls on equipment, not controlled by 1B01A, for the production of fibers, prepregs, preforms or composites.

6. In Supplement No. 1 to § 799.1 (the Commerce Control List), Category 1 (Materials), a Related ECCNs note is added immediately following ECCN 1B18A, as follows:

Related ECCNs: See 1B28B for MT controls on equipment for the production of propellants not controlled by 1B18A.

7. In Supplement No. 1 to § 799.1 (the Commerce Control List), Category 1 (Materials), a Related ECCNs note is added immediately following ECCN 1C01A, as follows:

Related ECCNs: See 1C21B for MT controls on other materials for reduced observables, not controlled by 1C01A, for applications usable for missile systems and subsystems.

8. In Supplement No. 1 to § 799.1 (the Commerce Control List), Category 1 (Materials), a Related ECCNs note is

added immediately following ECCN 1C02A, as follows:

Related ECCNs: See 1C22B for MT controls on tungsten, molybdenum, and alloys of these metals, not controlled by 1C02A, in the form of uniform spherical or atomized particles for the fabrication of rocket motor components.

9. In Supplement No. 1 to § 799.1 (the Commerce Control List), Category 1 (Materials), a Related ECCNs note is added immediately following ECCN 1C07A, as follows:

Related ECCNs: See 1C27B for MT controls on ceramic or graphite materials, not controlled by 1C07A, usable in missile systems.

10. In Supplement No. 1 to § 799.1 (the Commerce Control List), Category 1 (Materials), a Related ECCNs note is added immediately following ECCN 1C10A, as follows:

Related ECCNs: See 1C50E for NP/FP controls on fibrous and filamentary materials not controlled by 1C10A.

11. In Supplement No. 1 to § 799.1 (the Commerce Control List), Category 2 (Materials Processing), a Related ECCNs note is added immediately following ECCN 2B01A, as follows:

Related ECCNs: See 2B41E for NP controls on "numerically controlled" machine tools not controlled by 2B01A.

12. In Supplement No. 1 to § 799.1 (the Commerce Control List), Category 2 (Materials Processing), a Related ECCNs note is added immediately following ECCN 2B04A, as follows:

Related ECCNs: See 2B24B for MT/NP controls on "isostatic presses" not controlled by 2B04A.

13. In Supplement No. 1 to § 799.1 (the Commerce Control List), Category 2 (Materials Processing), a Related ECCNs note is added immediately following ECCN 2B06A, as follows:

Related ECCNs: See 2B46B for NP controls on dimensional inspection systems not controlled by 2B06A.

14. In Supplement No. 1 to § 799.1 (the Commerce Control List), Category 3 (Electronics Design, Development and Production), a Related ECCNs note is added immediately following ECCN 3A01A, as follows:

Related ECCNs: See 3A41E, 3A42E, and 3A43B for NP controls on capacitors, superconducting solenoidal electromagnets, and switching devices not controlled by 3A01A.

15. In Supplement No. 1 to § 799.1 (the Commerce Control List), Category 4 (Computers), a Related ECCNs note is added immediately following ECCN 4A01A, as follows:

Related ECCNs: See 4A21B for MT controls on electronic computers and related equipment, not controlled by 4A01A, that are designed or modified for airborne applications.

16. In Supplement No. 1 § 799,1 (the Commerce Control List), Category 6 (Sensors), a Regulated ECCNs note is added immediately following ECCN 6A02A, as follows:

Related ECCNs: See 6A22B and 6A42B for MT/NP controls on photosensitive components and electron tubes not controlled by 6A02A.

17. In Supplement No. 1 to § 799.1 (the Commerce Control List), Category 6 (Sensors), a Related ECCNs note is added immediately following ECCN 6A03A, as follows:

Related ECCNs: See 6A43B for NP controls on cameras, components, and photographic recording media not controlled by 6A03A.

18. In Supplement No. 1 to § 799.1 (the Commerce Control List), Category 6 (Sensors), a Related ECCNs note is added immediately following ECCN 6A08A, as follows:

Related ECCNs: See 6A28B, 6A29B, and 6A30B for MT controls on any of the following items not controlled by 6A08A: radar and laser radar systems, precision tracking systems, and integrated electronic systems for radar cross section measurement.

19. In Supplement No. 1 to § 799.1 (the Commerce Control List), Category 6 (Sensors), a Related ECCNs note is added immediately following ECCN 6D01A, as follows:

Related ECCNs: See 6D21B for MT controls on "software" specially designed for the "development" or "production" of equipment controlled by 6A02.a.1, a.3, and a.4, 6A22, 6A07.b and c, 6A28, or 6A30.

20. In Supplement No. 1 to § 799.1 (the Commerce Control List), Category 6 (Sensors), a Related ECCNs note is added immediately following ECCN 6D02A, as follows:

Related ECCNs: See 6D22B for MT controls on "software" specially designed for the "use" of equipment controlled by 6A02.a.1, a.3, and a.4, 6A22, 6A07.b and c, 6A2B, or 6A30.

21. In Supplement No. 1 to § 799.1 (the Commerce Control List), Category 6 (Sensors), a Related ECCNs note is added immediately following ECCN 6E01A, as follows:

Related ECCNs: See 6E21B for MT controls on technology for the "development" of equipment controlled by 6A22, 6A28, 6A29, or 6A30.

22. In Supplement No. 1 to Section 799.1 (the Commerce Control List), Category 6 (Sensors), a Related ECCNs note is added immediately following ECCN 6E02A, as follows:

Related ECCNs: See 6E22B for MT controls on technology for the "production" of equipment controlled by 6A22, 6A28, 6A29, or 6A30.

23. In Supplement No. 1 to § 799.1 (the Commerce Control List), Category 6 (Sensors), a Related ECCNs note is added immediately following ECCN 6E03A, as follows:

Related ECCNs: See 6E23B for MT controls on technology for the "use" of euipment controlled by 6A02.a.1, a.3, and a.4, 6A22, 6A07.b and c, 6A08, 6A28, 6A29, or 6A30.

24. In Supplement No. 1 to § 799.1 (the Commerce Control List), Category 7 (Navigation and Avionics), a Related ECCNs note is added immediately following ECCN 7A01A, as follows:

Related ECCNs: See 7A21B for MT controls on accelerometers, not controlled by 7A01A, that are designed for use in inertial navigation systems or in guidance systems of all types.

25. In Supplement No. 1 to § 799.1 (the Commerce Control List), Category 7 (Navigation and Avionics), a Related ECCNs note is added immediately following ECCN 7A02A, as follows:

Related ECCNs: See 7A22B for MT controls on gyros not controlled by 7A02A.

26. In Supplement No. 1 to § 799.1 (the Commerce Control List), Category 7 (Navigation and Avionics), a Related ECCNs note is added immediately following ECCN 7A03A, as follows:

Related ECCNs: See 7A23B for MT controls on inertial or other equipment, not controlled by 7A03A, using accelerometers or gyros described in 7A21B or 7A22B, and systems incorporating such equipment.

27. In Supplement No. 1 to § 799.1 (the Commerce Control List), Category 7 (Navigation and Avionics), a Related ECCNs note is added immediately following ECCN 7A04A, as follows:

Related ECCNs: See 7A24B for MT controls on gyro-astro compasses not controlled by 7A04A.

28. In Supplement No. 1 to § 799.1 (the Commerce Control List), Category 7 (Navigation and Avionics), a Related ECCNs note is added immediately following ECCN 7A05A, as follows:

Related ECCNs: See 7A25B for MT controls on Global Positioning System (GPO), or other satellite receivers, not controlled by 7A05A.

29. In Supplement No. 1 to § 799.1 (the Commerce Control List), Category 7 (Navigation and Avionics), a Related ECCNs note is added immediately following ECCN 7A06A, as follows:

Related ECCNs: See 7A26B and 7A27B for MT controls on any of the following equipment that is not controlled by 7A06A: airborne radar, airborne laser radar systems.

and passive sensors for determining bearing to specific electromagnetic sources.

30. In Supplement No. 1 to § 799.1 (the Commerce Control List), Category 7 (Navigation and Avionics), a Related ECCNs note is added immediately following ECCN 7B02A, as follows:

Related ECCNs: See 7B22B for MT controls on reflectometers and specially designed test, calibration, and alignment equipment and "production equipment".

31. In Supplement No. 1 to § 799.1 (the Commerce Control List), Category 7 (Navigation and Avionics), a Related ECCNs note is added immediately following ECCN 7E01A, as follows:

Related ECCNs: See 7E21B for MT controls on technology, not controlled under 7E01A, for the "development", "production", or "use" of equipment or "software" controlled under Category 7 for MT reasons.

32. In Supplement No. 1 to § 799.1 (the Commerce Control List), Category 7 (Navigation and Avionics), a Related ECCNs note is added immediately following ECCN 7E02A, as follows:

Related ECCNs: See 7E22B for MT controls on design technology for the protection of avionics and electrical subsystems against electromagnetic pulse (EMP) and electromagnetic interference (EMI) hazards from external sources.

33. In Supplement No. 1 to § 799.1 (the Commerce Control List), Category 9 (Propulsion Systems and Transportation Equipment), a Related ECCNs note is added immediately following ECCN 9A01A, as follows:

Related ECCNs: See 9A21B and 9A22B for MT controls on gas turbine aero engines not controlled by 9A01A, and for vehicles designed or modified for transporting or handling missile systems.

34. In Supplement No. 1 to § 799.1 (the Commerce Control List), Category 9 (Propulsion Systems and Transportation Equipment), a Related ECCNs note is added immediately following ECCN 9B01A, as follows:

Related ECCNs: See 9B21B for MT controls on specially designed production facilities and equipment, not controlled by 9B01A, for the systems, sub-systems, and components in missile systems.

35. In Supplement No. 1 to § 799.1 (the Commerce Control List), Category 9 (Propulsion Systems and Transportation Equipment), a Related ECCNs note is added immediately following ECCN 9B03A, as follows:

Related ECCNs: See 9B23B for MT controls on servo valves designed to operate in vibration environments.

36. In Supplement No. 1 to § 799.1 (the Commerce Control List), Category 9 (Propulsion Systems and Transportation Equipment), a Related ECCNs note is added immediately following ECCN 9B04A, as follows:

Related ECCNs: See 9B24B for MT controls on pumps, for liquid propellants, designed to operate in vibration environments.

37. In Supplement No. 1 to § 799.1 (the Commerce Control List), Category 9 (Propulsion Systems and Transportation Equipment), a Related ECCNs note is added immediately following ECCN 9B05A, as follows:

Related ECCNs: See 9E25B for MT controls on wind tunnels, and on related control systems, instrumentation, and automated data acquisition and processing equipment not controlled by 9B05A.

38. In Supplement No. 1 to § 799.1 (the Commerce Control List), Category 9 (Propulsion Systems and Transportation Equipment), a Related ECCNs note is added immediately following ECCN 9B06A, as follows:

Related ECCNs: See 9B26B for MT controls on vibration test equipment not controlled by 9B06A.

39. In Supplement No. 1 to § 799.1 (the Commerce Control List), Category 9 (Propulsion Systems and Transportation Equipment), a Related ECCNs note is added immediately following ECCN 9B07A, as follows:

Related ECCNs: See 9B27B for MT controls on test benches/stands capable of handling solid or liquid propellant rockets or rocket motors.

40. In Supplement No. 1 to § 799.1 (the Commerce Control List), Category 9 (Propulsion Systems and Transportation Equipment), a Related ECCNs note is added immediately following ECCN 9E01A, as follows:

Related ECCNs: See 9E21B for MT controls on technology, not controlled under 9E01A, for the "development", "production", or "use" of items controlled under Category 9 for MT reasons.

41. In Supplement No. 1 to § 799.1 (the Commerce Control List), Category 0 (Miscellaneous) is amended by revising the category heading that follows ECCN 9E96G and by adding a Note immediately following the heading, as follows:

Category 10—Miscellaneous

Note: Note that the Export Control Classification Numbers (ECCNs) in Category 10 begin with the number "0", instead of the number "10". This is done to ensure that every ECCN on the Commerce Control List has the same number of characters (five). Maintaining the same number of characters for every ECCN will assist exporters who use ECCNs in their computerized recordkeeping activities.

* * * * *

Dated: December 18, 1991.

James M. LeMunyon,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 91-30593 Filed 12-23-91; 8:45 am]

BILLING CODE 3510-DT-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Social Security Administration

20 CFR Part 401

RIN 0960-AC79

Blood Donor Locator Service

AGENCY: Social Security Administration, HHS.

ACTION: Final rules.

SUMMARY: We are issuing these final regulations to govern the Blood Donor Locator Service, which we will establish and conduct, as required by section 8008 of the Technical and Miscellaneous Revenue Act of 1988 (Pub. L. 100-647). Under these regulations, we will furnish to participating States at their request the last known personal mailing address (residence or post office box) of blood donors whose blood donation shows that they are or may be infected with the human immunodeficiency virus (HIV) which causes acquired immune deficiency syndrome, if the State or an authorized blood donation facility has been unable to locate the donors. If our records or those of the Internal Revenue Service (IRS) contain an adequate personal mailing address for the donor, we will provide it to the State so that the State or the blood donation facility can inform the donor that he or she may need medical care and treatment.

DATES: These rules are effective December 24, 1991.

FOR FURTHER INFORMATION CONTACT: Jack Schanberger, room 3-B-1 Operations Building, 6401 Security Boulevard, Baltimore, MD 21235, (301) 965-8471.

SUPPLEMENTARY INFORMATION: Section 8008 of Public Law 100-647, the Technical and Miscellaneous Revenue Act of 1988, amended section 205(c)(2) of the Social Security Act (the Act) and added section 1141. Section 8008 requires the Secretary of Health and Human Services (the Secretary) to establish and conduct a Blood Donor Locator Service (BDLS) under the direction of the Commissioner of Social Security. The purpose of the BDLS is to provide an additional means by which States and authorized blood donation

facilities can notify blood donors whose blood donations show that they are or may be infected with HIV which causes acquired immune deficiency syndrome and, therefore, may need medical care and treatment. The statute permits States to require a blood donor to furnish his or her social security number to a State agency or to an authorized blood donation facility. An authorized blood donation facility is one which, as required by sections 205(c)(2)(D)(iii)(I) and 1141(h)(1)(B) of the Act, is licensed or registered by the Food and Drug Administration. With the social security number, an authorized blood donation facility may request the State, pursuant to an arrangement with the Secretary, to contact the BDLS to obtain the donor's personal mailing address (residence or post office box). The State agency may also make such a request to the BDLS on its own behalf.

The Social Security Administration (SSA), on behalf of the Secretary, will enter into arrangements with an agency of an interested State under which SSA will accept requests for the last known personal mailing addresses (residence or post office box) of blood donors whose blood donations show that they are or may be infected with HIV. The State agency will be the agency within the State that has the duty or authority under State law relating to the public health, or otherwise has the duty or authority under State law to regulate blood donations.

Sections 1141 (a) and (b) of the Act provide that a State or an authorized blood donation facility within a State may request and receive from the BDLS address information concerning a blood donor who is or may be infected with HIV. Subsection (e) of section 1141 of the Act provides that the Secretary, in carrying out his duties and functions under the statute, shall enter into arrangements with State agencies for an agency to accept and to transmit to the Secretary and transmit to authorized blood donation facilities the requested information. We provide in these regulations that SSA, on behalf of the Secretary, will conduct the BDLS by arrangements with a State agency in each State which chooses to participate. Under these arrangements, the State agency will agree to accept requests for address information from authorized blood donation facilities and forward the requests to the BDLS. The State agency with which we will enter into arrangements may also submit a request for address information on its own behalf to the BDLS.

Section 1141(e)(1) of the Act provides that the Secretary shall enter into arrangements with State agencies to accept and to transmit to the Secretary requests for address information under this section and to accept and to transmit such information to authorized persons. We believe this provision provides authority for us to establish the BDLS so that it will only respond to requests for address information from State agencies with which we have entered into arrangements. The BDLS will not provide address information in response to requests from any person located in a State with which we have not entered into such arrangements, and the BDLS will not respond directly to blood donor facilities. We believe that this approach will foster the efficient and effective implementation of section 1141. The State agencies with which we will enter into these arrangements will be familiar with other State agencies and with blood donor facilities within their respective States which may qualify as authorized persons that may request address information under the statute. The State agencies with which we will enter into these arrangements will be able to assist the BDLS by verifying the qualifications of a blood donation facility as an authorized person and helping to monitor the compliance of authorized persons with these regulations.

We will process a request from the participating State agency if the State or the authorized blood donation facility cannot locate the donor at the address he or she provided at the time of the blood donation. After we receive an address request from a participating State agency, we will check our records of beneficiaries. If we do not have a current personal mailing address for the blood donor in question, we will forward the request to the IRS, which will check its tax records. Section 8008(c) of Public Law 100–647 also provides that the Secretary of the Treasury must give us taxpayer mailing address information when we need such information to comply with a BDLS request.

The BDLS provisions of the Act require that an authorized blood donation facility must provide for notification procedures and counseling of blood donors with positive antibody HIV tests. The legislative history of section 1141 of the Act indicates that Congress expects blood donation facilities which use the BDLS to make reasonable efforts at notification, but does not expect facilities to use extraordinary means to reach individuals who may have moved out of the area in which the facility is located. The legislative history further indicates that blood donation facilities would be permitted to use existing counseling programs or referrals to provide counseling for these donors and that new counseling programs would not be required. H.R. Rep. No. 100–795, 100th Cong., 2d Sess. 620 (1988).

Section 205(c)(2) of the Act as amended by section 8008 of Public Law 100–647 allows States to require anyone who donates blood within that State to furnish his or her social security number to the State or to an authorized blood donation facility. States and authorized blood donation facilities may utilize social security numbers for identification of blood donors. The social security number will be required information in requests to us for the donor's address.

Section 8008 of Public Law 100–647 also provides for stringent safeguards to protect the confidentiality and security of records of blood donors when address information is requested from the BDLS. These measures apply to States and authorized blood donation facilities that use the BDLS. They provide that State agencies and authorized blood donation facilities which use the BDLS must have a system for standardizing records pertaining to BDLS requests, must store blood donors' addresses and related blood donor records in a secure area that is safe from access by unauthorized persons, must restrict access to the records to persons whose duties require access and to whom disclosure may be made, must destroy identifying information after the donor has been notified, and must report to us, when requested, the procedures used to ensure confidentiality. We list these safeguards in these final regulations. We also provide in these final regulations that States and authorized blood donation facilities that use the BDLS must explain the applicable confidentiality standards and sanctions to personnel who will have access to any records pertaining to BDLS requests.

In addition to the confidentiality and security requirements for States and authorized blood donation facilities, section 8008 of Public Law 100–647 and these regulations state that SSA is required to destroy all identifying information in its records related to the address request after the BDLS has responded to the requesting State agency. Similarly, under section 8008 the IRS must destroy its records related to the request after it has responded to us in those situations where we requested the address from IRS tax records because our records did not contain a current personal mailing address. We

also state in these regulations that under section 8008 there are criminal penalties for unauthorized disclosure of information related to a blood donor. These criminal penalties will apply to any official or employee of the Federal Government, a State, or an authorized blood donation facility.

To monitor compliance with the confidentiality and security requirements of the statute and these regulations regarding address information received from the BDLS and related blood donor records, we provide in these regulations that we reserve the right to make onsite inspections of State agencies and authorized blood donation facilities. We also describe other measures we may take to ensure that the safeguards required by the law are being met. Section 1141(d)(5) of the Act requires that an authorized person, as defined in section 1141(h)(1) of the Act, which receives address information from the BDLS must furnish a report to the Secretary at such time and containing such information as he may prescribe, describing the procedures established and utilized for ensuring the confidentiality of address information provided by the BDLS and related blood donor records. Under the statute and these regulations, an authorized person, after receiving address information from the BDLS and either notifying or attempting to notify the donor, must destroy the address information and any record, list or compilation it established in connection with the request that indicates directly or indirectly the identity of the donor with respect to whom the request for address information was made.

Participation in the BDLS by State agencies and blood donation facilities is voluntary, but participants must agree to comply with the provisions of the statute and these regulations. If the address request of an authorized person does not comply with the statute and these regulations, we will not disclose address information, and the authorized person will have 60 days after receiving our notice of refusal to provide the address information within which to request administrative review. In these regulations, we explain the review process, including the timeframe within which we will process the request for review.

Public Law 100–647 requires the BDLS to furnish the "mailing address" of a blood donor who is or may be infected with HIV, but does not define the term "mailing address". Because of the sensitive nature of the information disclosed through the use of the BDLS, we will consider a donor's "mailing address" to be his or her personal mailing address (residence or post office box). Therefore, we will not release any other address, such as an employment address.

We are deleting the material currently in subpart F of 20 CFR part 401 relating to the disclosure of wage information for the Aid to Families with Dependent Children Program because this material is obsolete. Subpart F implemented section 411 of the Social Security Act, and section 411 was repealed by section 2651 of Public Law 98–369 (1984).

Discussion of Comments

On October 10, 1990, we published proposed rules in the **Federal Register** at 55 FR 41200 with a 60-day comment period. We received comments from four organizations involved with blood donations, two State Departments of Health, and an individual. The commenters, while supporting the BDLS, raised several questions and made suggestions that convinced us that several changes from the proposed rules were necessary. The comments and our responses are discussed below. Where more than one commenter addressed the same issue, we have discussed the issue and provided a single response.

Comment: Several commenters suggested that we should expand the locator service to include donors whose blood donation shows that they have other disease markers and to transfusion recipients who have been potentially exposed to HIV or these other disease agents.

Response: We have not adopted these comments because the statutory authority we have to conduct the locator service only authorizes us to provide address information for blood donors whose blood donations show that they are, or may be, infected with HIV. We, therefore, have no legal basis for extending the BDLS to other blood donors or to transfusion recipients.

Comment: One comment we received recommended that we revise proposed § 401.600(b)(2)(iii) to clarify that blood donation facilities would be permitted to use referrals to provide counseling services for donors infected with HIV.

Response: We believe that the Act and the congressional intent as stated in H.R. Rep. No. 100–795, 100th Cong., 2d Sess. 621 (1988) support this recommended change. We accordingly are modifying the final regulations to clarify that new counseling programs would not be required and that a blood donation facility may use existing programs or referrals to provide these services.

Comment: Several commenters questioned and objected to the requirement in proposed § 401.600(g)(5) that blood donation facilities would have to destroy the address information received from the BDLS and any related blood donor records after notifying or attempting to notify the donor without keeping a copy of this information for their files. Two commenters expressed the view that this requirement appears to be in conflict with regulations of the Food and Drug Administration that require blood centers to maintain blood donor records for a minimum of five and a half years. One commenter requested that the phrase "related blood donor records" be clarified.

Response: We appreciate these comments and we have revised § 401.600(g)(5) to clarify the information and the records that blood donation facilities and State agencies must destroy pursuant to section 1141 of the Act to protect the confidentiality of both the address information received from the BDLS and the records that are created when a request is made for this information.

Section 1141(d)(6) of the Act states that authorized persons "shall * * * destroy such address information and related blood donor records, upon completion of their use in providing the notification for which the information was obtained, so as to make such information and records undisclosable." The term "related blood donor records" is defined in section 1141(h)(1) as "any record, list or compilation which indicates, directly or indirectly, the identity of any individual with respect to whom a request for address information has been made pursuant to this section." Thus, that term refers to records related to the address request to the BDLS and does not refer to records which the Food and Drug Administration requires blood donation facilities to compile and maintain.

In their report on this legislation, the Committee on Ways and Means of the House of Representatives explains that blood donors would be protected by permitting access to address information only by State agencies and blood donation facilities meeting the requirements for confidentiality and security, and that the agencies and facilities that receive addresses through the BDLS "would be required to restrict access to blood donor records, provide for their security, and destroy them after use." See H.R Rep. No. 195, 100th Cong., 2d Sess. 621 (1988). The Committee explained further that the Secretary and the Secretary of the Treasury, as well as State agencies and blood donation facilities, would be required to destroy blood donor records after the address

information was transmitted. Thus section 1141(d)(6) prohibits blood donation facilities from retaining the information they receive from the BDLS and adding it to the donor records which they maintain for Food and Drug Administration purposes. The address information is to be used to attempt notification, and then destroyed.

Because, as noted above, the term "related blood donor records" does not include the records which the blood donation facilities must maintain for Food and Drug Administration purposes, the destruction of the address information does not mean the destruction of records required by the FDA. Although we believe that the proposed rule was consistent with the regulations of the Food and Drug Administration codified at 21 CFR 606.160(d) concerning the retention of records, in light of the public comments, we have clarified our final rules concerning this requirement.

Finally, we note that if a blood donation facility contacts a donor, using address information furnished by the BDLS, and the donor consents to having his or her address in other records maintained by the facility, the facility would not be legally precluded from updating its records and adding the correct address.

Comment: One organization expressed concern that it would not be able to use the BDLS in a given State if the State did not enter into a participation agreement with us, even though the organization meets the definition of an "authorized person."

Response: As we explain in the preamble, we believe that section 1141(e) of the Act supports the policy reflected in these regulations under which we will furnish address information only through arrangements with participating State agencies.

Comment: Several commenters requested that we clarify the provision in § 401.600(g)(6) of the proposed regulations concerning the onsite inspections we may conduct.

Response: We agree with the comment that the proposed rule did not clearly state that these onsite inspections would be for the limited purpose of determining whether the safeguards we have established for ensuring the confidentiality of address information received from the BDLS and related blood donor records are being met. We have modified paragraph (6) of § 401.600(g) to clarify that these inspections will be limited to this purpose.

Comment: One organization stated that our onsite inspections of blood donation facilities made pursuant to § 401.600(g)(6) should be announced in advance and clearly justified.

Response: We expect, that as a general rule, we will announce onsite inspections in advance and that such inspections will not be made frequently, and only when we believe that they are necessary or appropriate. See section 1141(d)(4) of the Act.

Comment: One organization suggested that we require that requests to the BDLS be sent to us by certified mail to avoid a breach in confidentiality.

Response: We do not believe there is an adequate need or justification for such a requirement. We believe instead that confidentiality can be best maintained through administrative controls within the agencies and organizations involved in the BDLS.

Comment: An organization suggested that blood donors not be required to furnish their social security numbers because some donors fear an invasion of privacy. One State's Department of Health says that State law prohibits blood donor facilities from disclosing the social security number of an unconsenting donor and the State currently has no statutory authority to require a donor's release of his or her social security number as a prerequisite to donating blood. Another organization pointed out that the requirement for a statement of HIV infection on a request to the BDLS was an unnecessary requirement.

Response: Section 1141(c) of the Act provides that a request to the BDLS must include the donor's social security number. Also, section 205(c)(2)(D)(i) of the Act provides that a State and an authorized blood donation facility may use social security numbers to identify blood donors. That section of the Act also provides that a State may require a blood donor to furnish the donor's social security number to the State or to an authorized blood donation facility. As a practical matter, SSA and IRS need the number to search their records for the donor's address. For these reasons, the final regulations require a blood donor's social security number as necessary information in a request to the BDLS. We have also retained in the final rules the requirement that a request for address information must contain a statement that the donor has tested positive for HIV or that the history of subsequent use of the donated blood or blood products indicates that the donor has or may have HIV. We believe that this information is necessary to ensure that we comply with the statutory restrictions that are applicable when we receive a request for address information that may be disclosed through the BDLS.

Comment: An organization asked how blood centers can be assured that SSA will maintain confidentiality and destroy records of donor information after processing has been completed.

Response: We intend to comply fully with the provisions of section 1141 on confidentiality and destruction of records, and we assume IRS will do the same. Both we and the IRS have decades of experience in maintaining, and disposing of, sensitive personal information in a manner that protects its confidentiality.

Comment: A State Department of Health noted that the BDLS should not undermine the State's efforts to maintain strict confidentiality and requested more information on procedures of the BDLS.

Response: As indicated in response to other comments, the BDLS rules on confidentiality are not intended to conflict with existing State procedures and Federal regulations on confidentiality of blood donor records. States will be contacted by Social Security Administration regional offices after these final rules have been published.

Except as indicated above, we are publishing the proposed rules essentially unchanged as final regulations.

Regulatory Procedures

Executive Order 12291

The Secretary has determined that this is not a major rule under Executive Order 12291, because the costs, if any, are expected to be negligible. Therefore, a regulatory impact analysis is not required.

Regulatory Flexibility Act

We certify that these regulations will not have a significant economic impact on a substantial number of small entities because they affect only the release of addresses of certain blood donors. Therefore, a regulatory flexibility analysis as provided in Public Law 96–354, the Regulatory Flexibility Act, is not required.

Paperwork Reduction Act

Section 401.600(d) of these final regulations imposes reporting requirements on the public, which are subject to Office of Management and Budget (OMB) clearance pursuant to the Paperwork Reduction Act of 1980. OMB has approved this information collection and assigned number 0960–0501.

(Catalog of Federal Domestic Assistance Program—No listing)

List of Subjects in 20 CFR Part 401

Administrative practice and procedure; Aid to families with dependent children; Freedom of information; Medicare; Old-Age, Survivors, and Disability Insurance; Privacy; Supplemental Security Income.

Dated: August 5, 1991.

Gwendolyn S. King,

Commissioner of Social Security.

Approved: September 10, 1991.

Louis W. Sullivan,

Secretary of Health and Human Services.

For the reasons set out in the preamble, subparts B and F of part 401 of 20 CFR chapter III are revised as follows:

PART 401—DISCLOSURE OF OFFICIAL RECORDS AND INFORMATION

1. The authority citation for subpart B is revised to read as follows:

Authority: Secs. 205(a), 1102, 1106, and 1141 of the Social Security Act; 5 U.S.C. 552 and 552a, 8 U.S.C. 1360, 26 U.S.C. 6103, 30 U.S.C. 923, 42 U.S.C. 405(a), 1302, 1306, and 1341.

2. Section 401.205 is revised to read as follows:

§ 401.205 Disclosures required by law.

We disclose information when a law specifically requires it. The Social Security Act requires us to disclose information for certain program purposes. These include disclosures to the Office of Inspector General, HHS, the parent Locator Service, and to States pursuant to an arrangement regarding use of the Blood Donor Locator Service. Also, there are other laws which require that we furnish other agencies information which they need for their programs. These include the Department of Veterans Affairs for its benefit programs, the Immigration and Naturalization Service to carry out its duties regarding aliens, the Railroad Retirement Board for its benefit programs, and to Federal, State, and local agencies administering Aid to Families with Dependent Children, Medicaid, unemployment compensation, food stamps, and other programs.

3–5. Subpart F is revised to read as follows:

Subpart F—Disclosures of Addresses by Blood Donor Locator Service

Authority: Secs. 205(c)(2), 1102, and 1141 of the Social Security Act; 42 U.S.C. 405(c)(2), 1302, and 1341, and 26 U.S.C. 6103.

§ 401.600 Blood Donor Locator Service

(a) *General.* We will enter into arrangements with State agencies under which we will furnish to them at their request the last known personal mailing addresses (residence or post office box) of blood donors whose blood donations show that they are or may be infected with the human immunodeficiency virus which causes acquired immune deficiency syndrome. The State agency or other authorized person, as defined in paragraph (b) of this section, will then inform the donors that they may need medical care and treatment. The safeguards that must be used by authorized persons as a condition to receiving address information from the Blood Donor Locator Service are in paragraph (g) of this section, and the requirements for a request for address information are in paragraph (d).

(b) *Definitions.* State means the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Commonwealth of Northern Marianas, and the Trust Territory of the Pacific Islands.

Authorized person means—

(1) Any agency of a State (or of a political subdivision of a State) which has duties or authority under State law relating to the public health or otherwise has the duty or authority under State law to regulate blood donations; and

(2) Any entity engaged in the acceptance of blood donations which is licensed or registered by the Food and Drug Administration in connection with the acceptance of such blood donations, and which provides for—

(i) The confidentiality of any address information received pursuant to these rules and section 1141 of the Social Security Act and related blood donor records;

(ii) Blood donor notification procedures for individuals with respect to whom such information is requested and a finding has been made that they are or may be infected with the human immunodeficiency virus; and

(iii) Counseling services for such individuals who have been found to have such virus. New counseling programs are not required, and an entity may use existing counseling programs or referrals to provide these services.

Related blood donor records means any record, list, or compilation established in connection with a request for address information which indicates, directly or indirectly, the identity of any indivudal with respect to whom a request for address information has been made pursuant to these rules.

(c) *Use of social security number for identification.* A State or an authorized person in the State may require a blood donor to furnish his or her social security number when donating blood. The number may then be used by an authorized person to identify and locate a donor whose blood donation indicates that he or she is or may be infected with the human immunodeficiency virus.

(d) *Request for address of blood donor.* An authorized person which has been unable to locate a blood donor at the address he or she may have given at the time of the blood donation may request assistance from the State agency which has arranged with us to participate in the Blood Donor Locator Service. The request to the Blood Donor Locator Service must—

(1) Be in writing;

(2) Be from a participating State agency either on its own behalf as an authorized person or on behalf of another authorized person;

(3) Indicate that the authorized person meets the confidentiality safeguards of paragraph (g) of this section; and

(4) Include the donor's name and social security number, the addresses at which the authorized person attempted without success to contact the donor, the date of the blood donation if available, a statement that the donor has tested positive for the human immunodeficiency virus according to the latest Food and Drug Administration standards or that the history of the subsequent use of the donated blood or blood products indicates that the donor has or may have the human immunodeficiency virus, and the name and address of the requesting blood donation facility.

(Approved by the Office of Management and Budget under control number 0960–0501.)

(e) *SSA response to request for address.* After receiving a request that meets the requirements of paragraph (d) of this section, we will search our records for the donor's latest personal mailing address. If we do not find a current address, we will request that the Internal Revenue Service search its tax records and furnish us any personal mailing address information from its files, as required under section 6103(m)(6) of the Internal Revenue Code. After completing these searches, we will provide to the requesting State agency either the latest mailing address available for the donor or a response stating that we do not have this information. We will then destroy the records or delete all identifying donor information related to the request and maintain only the information that we will need to monitor the compliance of authorized persons with the confidentiality safeguards contained in paragraph (g) of this section.

(f) *SSA refusal to furnish address.* If we determine that an authorized person

has not met the requirements of paragraphs (d) and (g) of this section, we will not furnish address information to the State agency. In that case, we will notify the State agency of our determination, explain the reasons for our determination, and explain that the State agency may request administrative review of our determination. The Commissioner of Social Security or a delegate of the Commissioner will conduct this review. The review will be based on the information of record and there will not be an opportunity for an oral hearing. A request for administrative review, which may be submitted only by a State agency, must be in writing. The State agency must send its request for administrative review to the Commissioner of Social Security, 6401 Security Boulevard, Baltimore, MD 21235, within 60 days after receiving our notice refusing to give the donor's address. The request for review must include supporting information or evidence that the requirements of these rules have been met. If we do not furnish address information because an authorized person failed to comply with the confidentiality safeguards of paragraph (g) of this section, the State agency will have an opportunity to submit evidence that the authorized person is now in compliance. If we then determine, based on our review of the request for administrative review and the supporting evidence, that the authorized person meets the requirements of these rules, we will respond to the address request as provided in paragraph (e) of this section. If we determine on administrative review that the requirements have not been met, we will notify the State agency in writing of our decision. We will make our determination within 30 days after receiving the request for administrative review, unless we notify the State agency within this 30-day time period that we will need additional time. Our determination on the request for administrative review will give the findings of fact, the reasons for the decision, and what actions the State agency should take to ensure that it or the blood donation facility is in compliance with these rules.

(g) *Safeguards to ensure confidentiality of blood donor records.* We will require assurance that authorized persons have established and continue to maintain adequate safeguards to protect the confidentiality of both address information received from the Blood Donor Locator Service and related blood donor records. The authorized person must, to the satisfaction of the Secretary—

(1) Establish and maintain a system for standardizing records which includes the reasons for requesting the addresses of blood donors, dates of the requests, and any disclosures of address information;

(2) Store blood donors' addresses received from the Blood Donor Locator Service and all related blood donor records in a secure area or place that is physically safe from access by persons other than those whose duties and responsibilities require access;

(3) Restrict access to these records to authorized employees and officials who need them to perform their official duties related to notifying blood donors who are or may be infected with the human immunodeficiency virus that they may need medical care and treatment;

(4) Advise all personnel who will have access to the records of the confidential nature of the information, the safeguards required to protect the information, and the civil and criminal sanctions for unauthorized use or disclosure of the information;

(5) Destroy the address information received from the Blood Donor Locator Service, as well as any records established in connection with the request which indicate directly or indirectly the identity of the individual, after notifying or attempting to notify the donor at the address obtained from the Blood Donor Locator Service; and

(6) Upon request, report to us the procedures established and utilized to ensure the confidentiality of address information and related blood donor records. We reserve the right to make onsite inspections to ensure that these procedures are adequate and are being followed and to request such information as we may need to ensure that the safeguards required in this section are being met.

(h) *Unauthorized disclosure.* Any official or employee of the Federal Government, a State, or a blood donation facility who discloses blood donor information, except as provided for in this section or under a provision of law, will be subject to the same criminal penalty as provided in section 7213(a) of the Internal Revenue Code of 1986 for the unauthorized disclosure of tax information.

[FR Doc. 91-30610 Filed 12-23-91; 8:45 am]
BILLING CODE 4190-29-M

Food and Drug Administration

21 CFR Part 106

[Docket No. 87N-0402]

Infant Formula Record and Record Retention Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its infant formula regulations with respect to records, and retention of records, that relate to various subjects, including, but not limited to, microbiological and nutrient testing, manufacturers' audits, and consumer complaints. This action is in response to the 1986 infant formula amendments to the Federal Food, Drug, and Cosmetic Act (the act). The amended regulations will help ensure a safe, wholesale, and sanitary sole source of nutrition for infants.

EFFECTIVE DATE: April 22, 1992.

FOR FURTHER INFORMATION CONTACT: Janice F. Oliver, Center for Food Safety and Applied Nutrition (HFF-310), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-485-0187.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 26, 1989 (54 FR 3783), FDA proposed to amend the record retention requirements in its infant formula regulations. This proposal was required to implement those provisions of the Drug Enforcement, Education, and Control Act of 1986 (Pub. L. 99-570) that are known as "the 1986 infant formula amendments" (the 1986 amendments) to the act. The agency proposed to provide for the retention of all records covered by 21 U.S.C. 350a(b)(4)(A) and (g). These records include, but are not limited to, all records:

1. Necessary to document that the food packaging materials used comply with section 402(a) of the act;
2. Pertaining to nutrient premixes;
3. Necessary to document compliance with proper quality control procedures;
4. Necessary to document appropriate nutrient levels in each batch of infant formula;
5. Necessary to document required infant formula nutrient testing at the final product stage;
6. Pertaining to distribution of infant formula;
7. Necessary to document microbiological quality and purity of infant formula;

8. Necessary to document each scheduled audit; and

9. Necessary to document appropriate handling of infant formula complaints.

In addition, the proposed amendments set out administrative requirements on where and how, and for what length of time, the records are to be maintained.

The proposal did not deal with the records that would need to be retained to demonstrate compliance with good manufacturing practices (referred to as "current good manufacturing practices," or "CGMP's," in this document) for infant formula. The agency intends to issue a proposal on CGMP's, and that proposal will include all necessary record and record retention requirements relevant to CGMP's.

Interested persons were given until March 27, 1989, to comment on the proposal. FDA received comments from a trade association suggesting several modifications to the proposed rule. A summary of the comments and FDA responses is set forth below.

II. General Comments

1. One comment suggested that proposed § 106.100(a) (21 CFR 106.100(a)) be revised to delete the summary list of records. The comment contended that the proposed summary was inconsistent with other FDA record retention provisions, added nothing substantive to the regulation, and created ambiguity.

The agency agrees with the comment and has revised § 106.100(a) accordingly. It has also made minor editorial changes in this provision.

2. One comment requested that FDA clarify the meaning of the phrase "shall maintain" that is used throughout the regulation. The comment interpreted this phrase to mean that manufacturers must maintain records either that they create or that come into their possession as a result of doing business. However, the comment objected if the phrase was intended to require that infant formula manufacturers obtain records created by companies other than the manufacturers themselves that would not come into the manufacturers' hands in the normal course of business. The comment was specifically concerned about a manufacturer's obligation to obtain all premix records.

The agency agrees that manufacturers need not obtain all records from other companies, and that infant formula manufacturers cannot be expected to obtain all premix testing records. Therefore, FDA has revised proposed § 106.100(c)(3) to reflect 21 U.S.C. 350a(b)(4)(A)(iii). It is the obligation of the premix supplier to maintain all records necessary to confirm the accuracy of all premix certifications and guarantees of analysis. Revised § 106.100(c)(3) is renumbered as § 106.100(d).

However, the regulations will require that infant formula manufacturers retain those certifications and guarantees of analysis that they receive from premix suppliers (21 U.S.C. 350a(b)(4)(A)(ii)) and all results of testing that the manufacturer or its contractors conduct to ensure that each nutrient premix is in compliance with the premix certificate and guarantee and all other specifications such as those pertaining to potential contaminants routinely provided by premix suppliers.

3. One comment noted that the 1986 amendments use the term "batch" and not "lot" and suggested that the term "batch" be used in lieu of the term "lot" wherever it appears in the regulation. The comment stated that the existing quality control regulations define "in-process batch."

The agency agrees with the comment and has revised § 106.100 accordingly.

4. One comment requested an additional 60 days to comply with the final rule. The comment contended that 120 days were needed to achieve effective planning and proper implementation of the new requirements.

The agency has decided to accept this comment. While this final rule does not impose any testing or manufacturing requirements, it does require that records be maintained in a specific manner. The agency agrees with the comment that compliance with the requirement of these regulations will be facilitated by a longer compliance period. Therefore, FDA concludes that a 120-day implementation date is more reasonable than the 60-day implementation date that FDA proposed, and has revised the effective date accordingly.

III. Food-Packaging Materials

5. One comment suggested that § 106.100(b) be revised to identify food-packaging material as "primary" food-packaging material to clarify that § 106.100(b) applies only to packaging materials that come into contact with the product.

The agency disagrees. Section 106.100(b) applies to all packaging materials that may cause an infant formula to be adulterated under section 402(a)(2)(C) of the act, whether or not the material comes into direct contact with the product. For example, adhesives and other components of packaging laminates that do not themselves come into direct contact with food have been shown to migrate to foods packaged therein, particularly when thermal processing is involved. However, to clearly identify the packaging materials to which § 106.100(b) applies, the agency has modified this section to read, "The manufacturer shall maintain all records that pertain to food-packaging materials subject to 21 CFR 174.5 and that bear on whether such materials would cause an infant formula to be adulterated within the meaning of section 402(a)(2)(C) of the act." Section 174.5 defines substances that, under conditions of CGMP, may be safely used as components of articles that contact food and the limitations on the use of these substances.

6. One comment questioned a manufacturer's responsibility to obtain all records resulting from tests by manufacturers of proprietary package coating materials.

As stated in the response to comment 2, manufacturers need not obtain all records from other companies. The agency, when necessary, can obtain information on proprietary package coating materials directly from packaging manufacturers. Infant formula manufacturers need only to obtain certification from their suppliers that the materials meet FDA requirements.

IV. Recall Records

7. One comment pointed out that the citation in proposed § 106.100(f) referring to subpart D of 21 CFR part 7 (Infant Formula Recall requirements) should be revised to reflect the change made in the final rule (54 FR 4006; January 27, 1989) subsequent to the publication of the proposal on § 106.100. The revised citation is subpart E of 21 CFR part 107.

The agency agrees with the comment and has revised what is now § 106.100(g) to refer to subpart E of 21 CFR part 107.

V. Microbiological Testing Records

A. The Proposal

In the preamble to the proposal published January 26, 1989 (54 FR 3783), FDA discussed specific microbiological guidelines for determining the microbiological quality and safety of infant formula. In addition, the agency referenced specific methods for making these determinations. However, FDA did not include the specific microbiological levels and methodology in the proposed codified material. Because of the way in which this material was presented, the comments reflected confusion as to the meaning of the proposal.

The comments to the proposal:

a. Objected to the testing for *Listeria monocytogenes;*

b. Suggested modification of the test for *Bacillus cereus;*

c. Suggested alternative testing for *Escherichia coli;*

d. Objected to the testing for *Clostridium perfringens;* and

e. Suggested a revised guideline that incorporates acceptable and unacceptable levels for each microorganism.

Comments regarding the microbiological guidelines in the proposal interpreted these guidelines as requiring testing for each identified organism, by a specific method, and as providing that if the level of an organism exceeded the guideline, the product would be judged to be violative. This interpretation is not correct.

The agency intended, through the proposal, to alert manufacturers and consumers to the fact that:

1. The 1986 amendments provided FDA investigators with authority to review all records pertaining to microbiological testing;

2. The overall microbiological quality and safety of the infant formula is the responsibility of the manufacturer, and that the agency had specific guidelines that it would use in judging product safety and quality on a case-by-case basis; and

3. The agency would use specific methods for microbiological testing. The agency listed these methods so that manufacturers could use them in their quality control procedures if they desired.

The agency did not include the specific microbiological levels in the proposed regulation because it believed that the scientific advances occurring at the time may require changes in the levels at some time in the future. However, at this time, the levels that the agency included in the preamble to the January 26, 1989 proposal, with the modifications suggested by comments, appear as appropriate as they did 3 years ago. Moreover, FDA has no reason to believe that there will be any need to change these levels in the near future.

B. The Record Requirement

To clarify this section of the regulation, the agency has revised § 106.100(h) (proposed as § 106.100(g)) to delete references to specific microorganisms and mention of the need to submit any alternate microbiological testing procedures. The regulation simply requires that a manufacturer maintain all records that pertain to the microbiological quality and purity of raw materials and finished powdered infant formula.

FDA intends to propose to adopt levels for microorganisms as factors to assure the quality and safety of infant formula in the CGMP regulation that FDA will publish soon.

C. Comments on the Microbiological Guidelines

Although FDA is not changing the proposed levels, the agency is revising the microbiological guidelines in response to the comments it has received. The revised guidelines will provide manufacturers with information on the levels of microorganisms that FDA considers to be acceptable for infant formulas. The following is a response to the comments on microbiological quality and safety that FDA has received.

8. One comment objected to the number of units to be sampled and the three-tier sampling plan for microbiological testing that FDA set out in the preamble to the proposal. The comment also objected to the need for different sampling plans for different microorganisms and suggested that compositing samples should be permitted to reduce the number of necessary analyses. The comment stated that the level of sampling and testing identified in the preamble would impose a financial burden on manufacturers that is not reflected in FDA's economic impact study.

The agency advises that manufacturers that wish to comply with the agency's microbiological guidelines need not use the sampling plan described in the preamble to the proposal for § 106.100. In the proposal, FDA identified the sampling plans and analytical methods that it will use in judging the microbiological safety and quality of powdered infant formula. The agency did not provide this information to delineate what methods or sampling plans may or may not be used by manufacturers. Manufacturers are free to use whatever sampling plans, methods, or steps within a method (such as compositing) that they believe are appropriate and that would be judged by scientific experts to be comparable to methods used by FDA.

9. One comment objected to what it saw as a requirement in proposed § 106.100(g) to test for *L. monocytogenes* because *L. monocytogenes* has not been found in infant formula. The comment did, however, acknowledge the public health significance of *L. monocytogenes* in milk products and suggested the recognition of alternate suitable methodology for *L. monocytogenes* if the agency decides to retain this requirement in the final rule.

As stated above, the agency has deleted all references to specific microorganisms in § 106.100(h) (proposed as 106.100(g)), and therefore testing for *L. monocytogenes* is not required by this final rule. However, because of the public health significance of *L. monocytogenes* in milk products, and the potential for this contaminant to be present in infant formula even though it has not actually been found, the agency will continue to test for *L. monocytogenes* in infant formula as well as for all the other microorganisms listed in Table 1. The microbiological guidelines presented in Table 1 at the end of this section will continue to contain a reference to *L. monocytogenes.*

With respect to the methodology used to test for *L. monocytogenes*, as stated in comment 8, a manufacturer is free to utilize whatever method it believes is appropriate. FDA cited in the preamble to the proposal the method that it intends to use when testing for *L. monocytogenes.* That method had been published in the **Federal Register** of November 1, 1988 (53 FR 44148), and corrected February 24, 1989 (54 FR 7995).

10. One comment suggested that what it saw as a proposed requirement to test for *B. cereus* should be modified to require testing only when test results for Aerobic Plate Count (APC) are equal to or greater than 1,000 organisms per gram.

As stated above, the agency has deleted all reference to specific microorganisms in § 106.100(h) (proposed as § 106.100(g)), and therefore testing for *B. cereus* is not required in this final rule. However, the agency has revised the microbiological guidelines presented in Table 1 at the end of this section to include *B. cereus* testing when an APC of 1,000 organisms per gram or more is found. *B. cereus* is one of the organisms that contributes to the microbiological level determined by the APC. The guideline for *B. cereus* is 1,000 organisms per gram. If the APC equals or exceeds 1,000 organisms per gram, the *B. cereus* level may exceed the guideline, and thus *B. cereus* testing should be conducted.

11. One comment suggested that what it saw as the testing requirement in proposed § 106.100(g) for *E. coli* be revised to provide greater flexibility and reduced cost by giving manufacturers the option to initially test for: (1) coliforms, (2) fecal coliforms, or (3) *E. coli.* The comment suggested that, if the agency were to accept this revision, it should provide that a manufacturer who elects to test initially for coliforms, and gets test results that are equal or greater

than 3 organisms per gram, must then test for the presence of fecal coliforms and *E. coli*. The comment also recommended that if this suggestion is accepted, the microbiological guidelines for coliform should be 10 organisms per gram, and the microbiological guidelines for fecal coliform and *E. coli* should be less than three organisms per gram. The comment advised that these suggestions are consistent with the International Commission on Microbiological Specifications for Foods and the Codex Alimentarius Commission recommendations.

As stated above, the agency has deleted all reference to specific microorganisms in § 106.100(h) (proposed as § 106.100(g)), and therefore testing for coliforms, fecal coliforms, or *E. coli* is not required in this final rule.

However, the agency agrees that providing the initial alternative of testing for coliforms or for fecal coliforms or *E. coli* is appropriate for the microbiological guidelines presented in Table 1 at the end of this section, provided that testing for fecal coliforms and *E. coli* is incorporated when coliform testing results are equal to or greater than three organisms per gram. Manufacturers are advised that the method the agency uses when testing for coliforms and fecal coliforms is presented in the Bacteriological Analytical Manual 1984, 6th edition, chapter 5. Therefore, FDA has revised the microbiological guidelines (presented in Table 1 at the end of this section) to provide the flexibility to test initially for either coliforms or fecal coliforms or *E. coli*. If coliform results equal or exceed three organisms per gram, the manufacturer should test for fecal coliforms and *E. coli*. If the product is initially tested for fecal coliforms or *E. coli*, and the results exceed the acceptable level of microorganisms per gram of dry product or "M" value, the product should be considered to have failed the test.

12. One comment suggested that the proposed testing requirement for *C. perfringens* in each batch be omitted because: (1) the organism is unable to multiply in the presence of oxygen; and (2) the organism is highly unlikely to proliferate during powdered infant formula processing, in the finished product form, or in feedings prepared from powdered infant formula.

As stated above, the agency has deleted all reference to specific microorganisms in § 106.100(h) (proposed as § 106.100(g)), and therefore testing for specific microorganism is not required by this final rule. However, the agency agrees that the combined testing for *Salmonella, L. monocytogenes, S. aureus, B. cereus*, APC, coliforms, fecal coliforms, and *E. coli* is sufficient to establish the microbiological safety and purity of an infant formula. Therefore, FDA has deleted *C. perfringens* from the microbiological guidelines presented at the end of this section.

13. One comment suggested that a product surveillance plan with two categories (acceptable (A) and unacceptable (U)) be established as the Infant Formula Microbiological Guidelines in lieu of the microbiological guidelines proposed in the preamble to the proposal. The comment suggested that test results indicating levels of microorganisms between A and U can be used as an alert to the manufacturer to investigate the raw materials and processing procedures to determine the necessary steps needed to reduce the microbiological levels.

The agency does not believe that it is useful to provide a listing of the microbiological levels that have no relation to inadequate quality or to health concerns and, therefore, to the possible initiation of regulatory action. The agency samples and tests infant formula to confirm that the product is acceptable for infant consumption. FDA is likely to view any level of organisms that is less than the level identified in Table 1 to acceptable. It is likely to view any level that exceeds the levels identified in Table 1 as representing a potential health or quality concern.

Therefore, based on comments 7 through 12, FDA had revised Table 1—Infant Formula Microbiological Guidelines—as follows:

TABLE [1].—INFANT FORMULA MICROBIOLOGICAL GUIDELINES

Bacteria	M [1]
1. *Salmonella*	0
2. *Listeria monocytogenes*	0
3. Coliform **	10
4. Fecal coliform **	3
5. *Escherichia coli* **	3
6. *Staphylococcus aureus*	3
7. *Bacillus cereus* *	10^3
8. Aerobic Plate Count (APC)	10^4

(M is the acceptable level of microorganisms per gram of the dry product).

[1] Fails test if any unit exceeds the value M.

B. cereus testing should be performed if APC results equal or exceed 10^3.

** Product may be tested initially for either coliforms or fecal coliforms or *E. coli*. Additional testing for fecal coliforms and *E. coli* should be performed if coliform results equal or exceed three organisms per gram. If the product is initially tested for fecal coliforms or *E. coli*, and the results exceed the M value, the product fails the test.

VI. Audit Records

14. One comment objected to proposed § 106.100(i), which requires that the audit records available for agency review must include written assurances from the manufacturer that regulatory scheduled audits by appropriately trained individuals are being conducted, and that the complete audit plans and procedures for the firm have been followed. The comment recommended that the proposed requirement be revised to read, "Upon request, a manufacturer must provide to FDA written assurance that regularly scheduled audits by appropriately trained individuals are being conducted." The comment further stated that it is unclear what "complete audit plans and procedures" means, and that the suggested change merely tracks the explicit language of the 1986 amendments.

The agency believes that a statement merely certifying that an audit has taken place is not sufficient to meet the requirement in the 1986 amendments "to provide to FDA written assurance" or regularly scheduled audits. The purpose of an audit is to determine whether the firm is complying with CGMP's, including quality control procedures, designed to prevent adulteration of infant formula (21 U.S.C. 350a(b)(2)(B)(iv)). FDA must be in a position to determine whether the audit conducted by a firm is adequate to fulfill this function. Therefore, the agency must know what the firm includes in its audit, what manufacturing practices and quality control procedures are to be audited (plans), and how, or by what methods, they are actually audited (procedures). The agency acknowledges that it does not have authority to obtain the results of the audit. Without knowledge of what is included in a firm's audit, however, the agency cannot determine whether the firm is complying with the act.

FDA has revised § 106.100(j) (proposed as § 106.100(i)) to define "audit plans" as the identification of the specific manufacturing and quality control procedures to be included in the audit, and "audit procedures" as the methods used to review each manufacturing and quality control procedure. Audits should include at least an annual review of all production, notification, and recordkeeping deviations from the firm specifications or standard operating procedures as well as a review of the functioning of production equipment, including computers; of microbiological and chemical contaminant controls for raw materials and final product; or nutrient level controls for raw materials and final product; and of controls on formulation and processing changes.

VII. Complaint Records

15. One comment requested that proposed § 106.100(j)(2) be revised to remove the provisions that relate to when an investigation into a complaint is necessary and to what must be included in the complaint file when an investigation is not necessary. The comment suggested revised wording to clarify that an investigation is not required for every complaint and to remove contradictory language regarding the definition of a "complaint."

The agency does not agree that it is appropriate to remove the provision that establishes when an investigation is necessary. This provision is appropriate to promote uniformity among manufacturers and to inform manufacturers of the types of complaints that FDA considers to warrant an investigation. However, FDA does agree that an investigation is not necessary for every complaint. The 1986 amendments are clear that FDA should be concerned with complaints and the investigation of complaints "* * * which may reveal the possible existence of a hazard to health." To be consistent with this provision, FDA has revised what is now § 106.100(k)(2) to state: "When a complaint shows that a hazard to health possibly exists, the manufacturer shall conduct an investigation into the validity of the complaint. When such an investigation is conducted, the manufacturer shall include in the complaint file the determination as to whether a hazard to health exists and the basis for that determination. No investigation is necessary when the manufacturer determines that there is no possibility of a hazard to health. When no investigation is necessary, the manufacturer shall incude in the complaint file the reasons that an investigation was found to be unnecessary and the name of the responsible person making that determination."

With respect to the suggestion that there is "contradictory language" regarding the definition of a complaint, the comment did not identify the language to which it was referring, and the agency was not able to identify any contradictory language. Therefore, FDA has not made any changes in response to this aspect of the comment.

16. One com nent objected to the requirement in proposed § 106.100(j)(4) that complaint files be maintained in two classes: (1) those complaints alleging that the infant became ill from consuming the product or required treatment by a health care provider; and (2) those complaints that involve a possible existence of a hazard to health but do not refer to an infant becoming ill or to the need for treatment by a health care provider. The comment stated that this requirement is unnecessarily burdensome, would increase the manufacturer's administrative expenses without serving any real purpose, and goes beyond FDA regulation of other products.

The agency disagrees. The 1986 amendments require that complaint files be maintained. Any system established to review and investigate product experience will involve reports of greater and lesser concern. The need to separate those reports of greater concern and importance is essential for the administrative efficiency of the system. This final rule establishes a uniform system for manufacturers to follow in creating such a separation. Therefore, FDA is retaining this requirement as proposed in what is now § 106.100(k)(4).

17. One comment objected to the requirements in proposed § 106.100(j)(5) that each complaint file maintained by the manufacturer include: "All the associated manufacturing records and complaint investigation records needed to evaluate the complaint." The comment stated that requiring all the associated manufacturing records would increase each complaint file to an unmanageable size without providing any increased ability to detect a problem, if one exists. The comment suggested revising the proposed requirement to permit the complaint file to include: "By reference or copy, the following items: complaint investigations records, follow up actions, review of manufacturing records when necessary, and other findings and conclusions."

The agency agrees that requiring all associated manufacturing records in each complaint file may result in large complaint files. However, the agency has a need, and is required by the 1986 amendments, to review and evaluate infant formula complaints. Therefore, the agency has concluded that all records needed to evaluate a complaint must be made readily available to the investigator.

However, FDA recognizes that the records need not be immediately available. Therefore, FDA has revised what is now § 106.100(k)(5)(v) to require that the complaint file include: "By reference or copy, all the associated manufacturing records needed to evaluate the complaint. When copies of such records are not maintained in the complaint file, they must be available within 24 hours when requested by an FDA official." Permitting the manufacturer 24 hours to obtain a requested file will ensure that FDA investigators have access to the records necessary to evaluate a complaint in a reasonable amount of time but not require that each file routinely include all associated records. This approach of obtaining records within 24 hours has been used by the agency in low acid canned food inspections, and manufacturers have met this limitation.

18. One comment objected to the requirement in proposed § 106.100(j)(6) that all records necessary to evaluate a complaint (particularly those that originate at the production site) be readily available for inspection at one alternate facility. The comment requested that the requirement of immediate availability of all records at one facility be omitted.

This comment reflects the fact that most infant formula manufacturers have several production sites but evaluate and investigate consumer complaints at only one facility. This facility may or may not be the production site for the product that is the subject of a complaint. The evaluation of consumer complaints at one facility permits the use of a specialized staff devoted to this activity, but it may also have the effect of separating the complaint review from the production records. It is therefore necessary either to permit sufficient time for manufacturers to obtain the files from the production facility for review by an FDA investigator or to require that all records be maintained at one facility.

The agency agrees that immediate availability of all records at one facility may be overly burdensome to manufacturers. The revision of the final rule to permit 24 hours for manufacturers to provide all records establishes a timeframe for providing the records necessary for agency review that is acceptable to the agency, yet will not result in an unnecessarily burdensome requirement for manufacturers. In addition, the final rule has retained the provision making electronic retrieval of records from other locations a means of meeting the requirements of this regulation (§ 106.100(l)). Thus, all records need not be routinely maintained at one site if they can be retrieved from production sites when an FDA investigator has need to review such files. However, the provision that permits manufacturers to maintain records of consumer complaints at one centralized facility does not permit manufacturers to refuse to permit FDA to review existing

consumer complaint files that are maintained at facilities other than the centralized facility. All consumer complaint files, including summaries and any other reports or files, maintained at the production facility or at any other facility must be made available to investigators. Section 106.100(k)(6) has been clarified to reflect this fact.

VIII. Record Retention

19. One comment objected to the provision in proposed § 106.100(m) that requires that manufacturers retain records for 1 year after the expiration of the shelf life of the infant formula or 3 years from the date of manufacture, whichever is longer. The comment suggested deletion of the requirement to retain records for 3 years from the date of manufacture. The comment stated that this provision exceeded FDA authority under the 1986 amendments.

The agency disagrees. The statute states in 21 U.S.C. 350a(4)(B)(i) that "* * * records shall be retained for at least 1 year after the expiration of the shelf life * * *." It does not limit retention of records to a maximum of 1 year after the expiration of the shelf life. The 3-year requirement from the date of manufacture is thus consistent with the statute. It is also consistent with 21 CFR 113.100 which requires the retention of processing records for low-acid canned foods, including liquid infant formula, for the same amount of time. Therefore, by retaining the requirement as proposed in what is now § 106.100(n), FDA is establishing a single record retention period for all infant formula records.

IX. Record for Public Health Evaluation

20. One comment suggested deleting proposed § 106.100(n), which requires that manufacturers maintain quality control records that contain sufficient information to permit a public health evaluation of any batch of infant formula. The comment stated that, as written, this section is duplicative, unnecessary, and confusing and can be interpreted to require that quality control records must be maintained ad infinitum.

The agency disagrees. This requirement is identical to the requirement in § 106.100(a) in the existing infant formula quality control regulation. Because the existing § 106.100 will be eliminated when this final rule becomes effective, inclusion of proposed § 106.100(n) merely continues the existing quality control requirement. The comment did not provide any showing that the existing provision causes duplication and confusion, and the agency is not aware of any duplication or confusion that has resulted from this provision. For this reason FDA is retaining § 106.100(n), renumbered as § 106.100(o), as proposed.

X. Editorial Suggestions

21. Minor editorial revisions were suggested to refer to "manufacturers" rather than "manufacturers of infant formula" and to "the act" rather than the Food, Drug, and Cosmetic Act because these terms are defined in other paragraphs in part 106.

The agency agrees with these comments and has revised § 106.100 accordingly. It has also made several additional minor editorial changes in this regulation.

XI. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the proposed rule on January 26, 1989 (54 FR 3783). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

XII. Economic Impact

In accordance with the Regulatory Flexibility Act (Pub. L. 96–354) and Executive Order 12291, the economic effects of this rule have been analyzed. FDA believes most of the records required by this rule are currently being maintained, and that those records concerning activity mandated by the 1986 amendments would be maintained in the absence of this rule. The additional cost of maintaining the complaint files in the required manner is also expected to be minimal. Finally, the additional burden posed by the 3 years from the date of manufacture record retention requirement is expected to be minimal; the statute itself requires retention of records for 1 year past the shelf-life of the product, and the average shelf-life for powdered and liquid infant formula is 2 and 1.5 years respectively. Furthermore, liquid infant formula, which comprises 90 percent of the market, is already required to retain records for 3 years from date of manufacture under the low acid canned food regulations. FDA accordingly expects the overall cost of this rule to be minimal.

Therefore, FDA certifies in accordance with section 605(b) of the Regulatory Flexibility Act that no significant economic impact on a substantial number of small entities will derive from this action. Further in accordance with Executive Order 12291, FDA certifies that this final rule will not result in a major rule as defined by that order.

XIII. Paperwork Reduction Act of 1980

Section 106.100 of this final rule contains collection of information requirements. As required by section 3504(h) of the Paperwork Reduction Act of 1980, FDA submitted a copy of this final rule to the Office of Management and Budget (OMB) for its review of this collection of information requirements. These requirements have been approved under OMB number 0910–0256.

Other organizations and individuals desiring to submit comments on the collection of information requirements should direct them to FDA's Dockets Management Branch (address above) and to the Office of Information and Regulatory Affairs, OMB Rm. 3208, New Executive Office Bldg., Washington, DC 20503, Attn: Desk Officer for FDA.

List of Subjects in 21 CFR Part 106

Food grades and standards, Infants and children, Nutrition, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 106 is amended to read as follows:

PART 106—[AMENDED]

1. The authority citation for 21 CFR part 106 continues to read as follows:

Authority: Secs. 201, 412, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 350a, 371).

2. Section 106.100 is revised to read as follows:

§ 106.100 Records.

(a) Every manufacturer of infant formula shall maintain the records specified in this regulation in order to permit the Food and Drug Administration to determine whether each manufacturer is in compliance with section 412 of the Federal Food, Drug, and Cosmetic Act (the act).

(b) The manufacturer shall maintain all records that pertain to food-packaging materials subject to § 174.5 of this chapter and that bear on whether such materials would cause an infant formula to be adulterated within the meaning of section 402(a)(2)(C) of the act.

(c) The manufacturer shall maintain all records that pertain to nutrient premix testing that it generates or receives. Such records shall include, but are not limited to:

(1) Any results of testing conducted to ensure that each nutrient premix is in compliance with the premix certificate and guarantee and specifications that have been provided to the manufacturer by the premix supplier, including tests conducted when nutrients exceed their expiration date or shelf life (retest date).

(2) All certificates and guarantees given by premix suppliers concerning the nutrients required by section 412(i) of the act and § 107.100 of this chapter.

(d) The premix supplier shall maintain the results of all testing conducted to provide all certificates and guarantees concerning nutrient premixes for infant formulas. Such records shall include but are not limited to:

(1) The results of tests conducted to determine the purity of each nutrient required by section 412(i) of the act or § 107.100 of this chapter and any other nutrient listed in the certificate and guarantee;

(2) The weight of each nutrient added;

(3) The results of any quantitative tests conducted to determine the amount of each nutrient certified or guaranteed; and

(4) The results of any quantitative tests conducted to identify the nutrient levels present when nutrient premixes exceed their expiration date or shelf life (retest date).

(e) The manufacturer shall maintain all records necessary to ensure proper nutrient quality control in the manufacture of infant formula products. Such records shall include the results of any testing conducted to verify that each nutrient required by section 412(i) of the act or § 107.100 of this chapter is present in each batch of infant formula at the appropriate concentration. This requirement pertains to ingredients, in process batch and finished product from the time of manufacture through its expiration date.

(f) The manufacturer shall maintain all records necessary to ensure required nutrient content at the final product stage. Such records shall include, but are not limited to, testing results for vitamins A, B_1 (thiamine), C, and E for each batch of infant formula. "Final product stage" means the point in the manufacturing process prior to distribution at which the infant formula is homogenous and not subject to further degradation from the manufacturing process.

(g) The manufacturer shall maintain all records pertaining to distribution of the infant formula. Such records shall include, but not be limited to, all information and data necessary to effect and monitor recalls of the manufacturer's infant formula products in accordance with subpart E of part 107 of this chapter.

(h) The manufacturer shall maintain all records pertaining to the microbiological quality and purity of raw materials and finished powdered infant formula.

(i) [Reserved]

(j) The manufacturer shall maintain all records pertaining to regularly scheduled audits, including audit plans and procedures. Audit plans identify the specific manufacturing and quality control procedures to be reviewed. Audit procedures are the methods used to review the manufacturing and quality control procedures. Records of audits shall include the information and data necessary for a determination as to whether the manufacturer complies with the current good manufacturing practices and quality procedures identified in parts 106, 107, 109, 110, and 113 of this chapter. The records shall include written assurances from the manufacturer that regularly scheduled audits are being conducted by appropriately trained individuals who do not have any direct responsibility for the manufacture or production of infant formula, and that the complete audit plans and procedures for the firm have been followed. The actual written reports of the audits need not be made available.

(k) The manufacturer shall maintain procedures describing how all written and oral complaints regarding infant formula will be handled. The manufacturer shall follow these procedures and shall include in them provisions for the review of any complaint involving an infant formula and for determining the need for an investigation of the possible existence of a hazard to health.

(1) For purposes of this section, every manufacturer shall interpret a "complaint" as any communication that contains any allegation, written or oral, expressing dissatisfaction with a product for any reason, including concerns about the possible existence of a hazard to health and about appearance, taste, odor, and quality. Correspondence about prices, package size or shape, or other matters that could not possibly reveal the existence of a hazard to health shall not, for compliance purposes, be considered a complaint and therefore need not be made available to an FDA investigator.

(2) When a complaint shows that a hazard to health possibly exists, the manufacturer shall conduct an investigation into the validity of the complaint. Where such an investigation is conducted, the manufacturer shall include in its file on the complaint the determination as to whether a hazard to health exists and the basis for that determination. No investigation is necessary when the manufacturer determines that there is no possibility of a hazard to health. When no investigation is necessary, the manufacturer shall include in the record the reason that an investigation was found to be unnecessary and the name of the responsible person making that determination.

(3) When there is a reasonable possibility of a causal relationship between the consumption of an infant formula and an infant's death, the manufacturer shall, within 15 days of receiving such information, conduct an investigation and notify the agency as required in § 106.120(b).

(4) The manufacturer shall maintain in designated files all records pertaining to the complaints it receives. The manufacturer shall separate the files into two classes:

(i) Those complaints that allege that the infant became ill from consuming the product or required treatment by a physician or health-care provider.

(ii) Those complaints that may involve a possible existence of a hazard to health but do not refer to an infant becoming ill or the need for treatment by physician or a health care provider.

(5) The manufacturer shall include in a complaint file the following information concerning the complaint:

(i) The name of the infant formula;

(ii) The batch number;

(iii) The name of complainant;

(iv) A copy of the complaint or a memo of the telephone conversation or meeting and all correspondence with the complainant;

(v) By reference or copy, all the associated manufacturing records and complaint investigation records needed to evaluate the complaint. When copies of such records are not maintained in the complaint file, they must be available within 24 hours when requested by an FDA official.

(vi) All actions taken to follow up on the complaint; and

(vii) All findings and evaluations of the complaint.

(6) The manufacturer should maintain the files regarding infant formula complaints at the establishment where the infant formula was manufacturer, processed, or packed. When the manufacturer wishes to maintain all consumer complaints for the entire firm at one location other than at the facility

where an infant formula was manufactured, processed, or packed, the manufacturer may do so as long as all records required by this section are available within 24 hours of request for inspection at that facility. However, all records of consumer complaints, including summaries, any reports, and any files, maintained at the manufacturing facility or at any other facility shall be made available to investigators for review and copying upon request.

(l) The manufacturer shall make readily available for authorized inspection all records required under this part or copies of such records. Records shall be available at any reasonable time at the establishment where the activities described in such records occurred. (Infant formula complaint files may be maintained at one facility, as provided in § 106.100(k)(6), if all required records are readily available at that facility.) These records or copies thereof shall be subject to photocopying or other means of reproduction as part of such inspection. Records that can be immediately retrieved from another location by electronic means shall be considered as meeting the requirements of this paragraph.

(m) Records required under this part may be retained either as original records or as true copies such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records. Where reduction techniques, such as microfilming are used, suitable reader and photocopying equipment shall be readily available.

(n) Production control, product testing, testing results, complaints, and distribution records necessary to verify compliance with parts 106, 107, 109, 110, and 113 of this chapter, or with other appropriate regulations, shall be retained for 1 year after the expiration of the shelf life of the infant formula or 3 years from the date of manufacture, whichever is greater.

(o) The manufacturer shall maintain quality control records that contain sufficient information to permit a public health evaluation of any batch of infant formula.

David A. Kessler,

Commissioner of Food and Drugs.

Dated: September 27, 1991.

Louis W. Sullivan,

Secretary of Health and Human Services

[FR Doc. 91-30716 Filed 12-23-91; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Lincomycin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to remove those portions of the regulations reflecting approval of two new animal drug applications (NADA's); one held by Ag-Mark, Inc., and the other held by Quali-Tech, Inc. The NADA's provide for the manufacture of Type B medicated feeds containing lincomycin. In a notice published elsewhere in this issue of the **Federal Register**, FDA is withdrawing approval of the NADA's.

EFFECTIVE DATE: January 3, 1992.

FOR FURTHER INFORMATION CONTACT: Mohammad I. Sharar, Center for Veterinary Medicine (HFV-216), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 301-295-8749.

SUPPLEMENTARY INFORMATION: In a notice published elsewhere in this issue of the **Federal Register**, FDA is withdrawing approval of NADA 133-035 held by Ag-Mark, Inc., P.O. Box 127, Teachey, NC 28464 and NADA 132-925 held by Quali-Tech, Inc., 318 Lake Hazeltine Dr., Chaska, MN 55318-1093. These NADA's provide for the manufacture of Type B medicated feeds containing lincomycin.

This final rule removes 21 CFR 558.325 (a)(8) and (a)(14) to reflect the withdrawal of approval of these NADA's.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

§ 558.325 [Amended]

2. Section 558.325 *Lincomycin* is amended by removing and reserving paragraphs (a)(8) and (a)(14).

Dated: December 17, 1991.

Gerald B. Guest,

Director, Center for Veterinary Medicine.

[FR Doc. 91-30717 Filed 12-23-91; 8:45 am]

BILLING CODE 4160-01-M

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 2610

Payment of Premiums: Correction

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule; correction.

SUMMARY: This document corrects a final rule that appeared in the **Federal Register** of Friday, October 18, 1991 (at 52 FR 52192), amending the Pension Benefit Guaranty Corporation's regulation on Payment of Premiums (29 CFR part 2610) to reflect a statutorily mandated increase in the PBGC premium rates applicable to single-employer plans. The amendment omitted a change to the premium rate figures in one section of the regulation. This action is needed to correct that omission.

FOR FURTHER INFORMATION CONTACT: Harold J. Ashner, Assistant General Counsel, Office of the General Counsel (22500), Pension Benefit Guaranty Corporation, 2020 K Street NW., Washington, DC 20006; 202-778-8850 (202-778-8859 for TTY and TDD). (These are not toll-free numbers.)

SUPPLEMENTARY INFORMATION: On October 18, 1991 (52 FR 52192), the Pension Benefit Guaranty Corporation ("PBGC") published in the **Federal Register** an amendment to its regulation on Payment of Premiums (29 CFR part 2610) to reflect a statutorily mandated increase in the PBGC premium rates applicable to single-employer plans. The amendment omitted a change to the premium rate figures in 29 CFR 2610.24(d). Accordingly, FR Doc. 91-25141, appearing on page 52192 in the issue of October 18, 1991, is corrected by adding, at the bottom of column 1 on page 52193, the following:

PART 2610—[AMENDED]

§ 2610.24 [Amended]

5. Section 2610.24 is amended by revising the words "the lesser of $34 or" in paragraph (d) thereof to read "$34 (for premium payment years beginning in 1988, 1989, or 1990) or $53 (for premium payment years beginning on or after January 1, 1991) or, if less,".

Dated: December 18, 1991.

James B. Lockhart III,

Executive Director, Pension Benefit Guaranty Corporation.

[FR Doc. 91-30699 Filed 12-23-91; 8:45 am]

BILLING CODE 7708-01-M

DEPARTMENT OF DEFENSE

Department of the Navy

32 CFR Part 701

Availability of Department of the Navy Records and Publication of Department of the Navy Documents Affecting the Public

AGENCY: Department of the Navy, DOD.

ACTION: Final rule.

SUMMARY: This rule sets forth amended regulations pertaining to the Department of the Navy's Freedom of Information Act Program. The rule reflects changes in the Secretary of the Navy Instruction 5720.42 series from which it is derived.

EFFECTIVE DATE: December 24, 1991.

FOR FURTHER INFORMATION CONTACT: Mrs. Doris M. Lama (OP-09B30P), Office of the Chief of Naval Operations, Washington, DC 20350-2000, Telephone: (703) 614-2004/2817.

SUPPLEMENTARY INFORMATION: Pursuant to the authority cited below, the Department of the Navy amends 32 CFR part 701, subparts A, B, C, and D derived from the Secretary of the Navy Instruction 5720.42 series, which implements within the Department of the Navy the provisions of Department of Defense Directives 5400.7 and 5400.7-R series, Department of Defense Freedom of Information Act Program (32 CFR part 286). This rule is being published by the Department of the Navy for guidance and interest of the public in accordance with 5 U.S.C. 552(a)(1). It has been determined that invitation of public comment on these changes to the Department of the Navy's implementing instruction prior to adoption would be impracticable and unnecessary, and it is therefore not required under the public rulemaking provisions of 32 CFR parts 286 and 701, subpart E. Interested persons, however, are invited to comment in writing on this amendment. All written comments received will be considered in making subsequent amendments or revisions to 32 CFR part 701, subparts A, B, C, and D, or the instruction upon which it is based. Changes may be initiated on the basis of comments received. Written comments should be addressed to Mrs. Doris M. Lama (OP-09B30P), Office of the Chief of Naval Operations, Washington, DC 20530-2000. It has been determined that this final rule is not a "major rule" within the criteria specified in section 1(b) of Executive order 12291 and does not have substantial impact on the public.

List of Subjects in 32 CFR Part 701

Administrative practice and procedure, Freedom of Information, Privacy.

Accordingly, 32 CFR part 701 is amended as follows:

PART 701—AVAILABILITY OF DEPARTMENT OF THE NAVY RECORDS AND PUBLICATION OF DEPARTMENT OF THE NAVY DOCUMENTS AFFECTING THE PUBLIC

1. The authority citation for 32 CFR part 701 continues to read as follows:

Authority: 5 U.S.C. 552.

2. Subparts A, B, C, and D are revised to read as follows:

Subpart A—Department of the Navy Freedom of Information Act Program

Sec.

Subpart B—FOIA Exemption Guidelines

Subpart C—Addresses for Department of the Navy Records and Locations for Public Inspection

Subpart D—Fee Guidelines

* * * * *

Subpart A—Department of the Navy Freedom of Information Act Program

§ 701.1 Purpose.

Subparts A, B, C, and D of this part implement the Freedom of Information Act (5 U.S.C. 552), and the Department of Defense Directives 5400.7 and 5400.7-R series[1], Department of Defense Freedom of Information Act Program, (See 32 CFR part 286) and promote uniformity in the Department of the Navy Freedom of Information Act (FOIA) Program. It is written to provide guidance to members of the public on how and where to submit FOIA requests and appeals within the Department of the Navy.

§ 701.2 Applicability.

Subparts A, B, C, and D of this part apply throughout the Department of the Navy. It governs disclosure of agency records to "any person," which means that any individual, to include foreign citizens, partnerships, corporations, associations and foreign, state, or local governments, may use the FOIA to obtain information. The exception to that policy is that it does not apply to Federal agencies or to fugitives from justice.

(a) *Requests from state or local government officials.* Requests from state or local government officials for naval records are treated the same as any other requester.

(b) *Requests from foreign governments.* Requests from foreign governments for naval records are treated the same as any other requester. However, requests from foreign governments that do not invoke the FOIA shall be referred to appropriate foreign disclosure channels and the requester so notified.

(c) *Privileged release to U.S. Government officials.* Naval records may be authenticated and released to U.S. Government officials if they are requesting them on behalf of Federal governmental bodies, whether

[1] Copies may be obtained if needed, from the U.S. Naval Publications and Forms Center, Attn: Code 1053, 5801 Tabor Avenue, Philadelphia, PA 19120.

legislative, executive, administrative, or judicial. For example:

(1) To a committee or subcommittee of Congress, or to either House sitting as a whole.

(Note: Requests from Members of Congress who are not seeking records on behalf of a Congressional Committee, Subcommittee, or either House sitting as a whole, but on behalf of their constituents, are treated the same as any other requester).

(2) To the Federal courts, whenever ordered by officers of the court as necessary for the proper administration of justice.

(3) To other Federal agencies, both executive and administrative, as determined by the head of a naval activity or designee.

In those instances, naval activities shall mark the records as "Privileged" and "Exempt from Public Disclosure." Any special handling instructions shall also be annotated on the records. Because such releases are not made under the provisions of the FOIA, they do not impact on future decisions to release/deny requests for the same records to other requesters.

(d) *Publication and public availability of special classes of records.* The requirements of 5 U.S.C. 552 that certain classes of Department of the Navy regulatory, rulemaking, and organizational records must be published in the **Federal Register** for the guidance of the public and made available for public inspection and copying are implemented in 32 CFR part 701, subpart C.

(e) *Public affairs regulations.* Subparts A, B, C, and D of this part are intended to complement, not restrict, the conduct of Department of the Navy public affairs, media relations, community relations and internal relations functions and practices authorized in Secretary of the Navy Instruction 5720.44 series, "Department of the Navy Public Affairs Regulations." Should the practices authorized in that instruction conflict in any respect, the provisions of these subparts shall be controlling.

(f) *U.S. Navy Regulations.* Release of a record to a member of the public under FOIA shall be deemed to have occurred in the discharge of official duties (Article 1120, U.S. Navy Regulations (1990)). Process a request by a member of the public under the instructions outlined in Section 3 of Chapter 11, U.S. Navy Regulations.

(g) *Other directives.* The following directives, and other directives and instructions cited in part 701, to the extent they do not conflict, provide additional information relating to subparts A, B, C, and D of this part. Should the practices authorized in the directives conflict in any respect, the provisions of these subparts shall be controlling.

(1) Marine Corps Manual, paragraph 1015 (NOTAL); Marine Corps Order P5720.56, Availability to the Public of Marine Corps Records (NOTAL); and for Headquarters, U.S. Marine Corps, HQO P5000.12, Chapter 10 (NOTAL) and HQO 5720.9 (NOTAL).

(2) Federal Personnel Manual, chapters 293, 294, 297, 335, 339, and 713 (NOTAL)—release of information from active and inactive civilian personnel records.

(3) Manual of the Medical Department, U.S. Navy (NAVMED P-117), Chapters 23-70 through 23-79 (NOTAL) release of information from active and inactive medical records.

(4) JAGINST 5800.7C, Manual of the Judge Advocate General (JAGMAN), Chapter V (NOTAL).

(h) *Relationship between FOIA and the Privacy Act (PA).* Not all requesters are knowledgeable of the appropriate statutory authority to cite when requesting records. In some instances, they may cite neither Act, but will imply one or both Acts. For those reasons, the following guidelines are provided to ensure that requesters receive the greatest amount of access rights under both Acts.

(1) Requesters who seek records about themselves contained in a PA system of records and who cite or imply PA, will have their requests processed under the provisions of PA (see subpart F of this part).

(2) Requesters who seek records about themselves which are not contained in a PA system of records and who cite or imply PA, will have their requests processed under FOIA provisions, since they have no access under PA.

(3) Requesters who seek records about themselves which are contained in a PA system of records and who cite or imply FOIA or both Acts will have their requests processed under the time limits of FOIA and the exemptions and fees of PA. That is appropriate since greater access will be received under PA.

(4) Requesters who seek access to agency records and who cite or imply PA and FOIA, will have their requests processed under FOIA.

(5) Requesters who seek access to agency records and who cite or imply FOIA, will have their requests processed under FOIA.

If the requester has failed to cite the appropriate Act, naval activities shall apprise the requester in the final response under which Act his/her request was processed.

§ 701.3 Definitions.

(a) *FOIA request.* A written request for Department of the Navy records, made by "any person," including a member of the public (U.S. or foreign citizen), an organization, or a business, but not including a Federal agency or a fugitive from the law that either explicitly or implicitly invokes 5 U.S.C. 552, Department of Defense Directives 5400.7 and 5400.7-R series, "Department of Defense Freedom of Information Act Program" (see 32 CFR part 286) and/or subparts A, B, C, and D of this part.

(b) *Agency record.* (1) The products of data compilation, such as all books, papers, maps, and photographs, machine readable materials, or other documentary materials, regardless of physical form or characteristics, made or received by an agency of the United States Government under Federal law or in connection with the transaction of public business and in Department of the Navy's possession and control at the time a FOIA request is made.

(2) The following are not included in this definition:

(i) Objects or articles, such as structures, furniture, paintings, sculpture, three-dimensional models, vehicles, equipment, and parts of wrecked aircraft and ships, whatever their historical value, or value as evidence.

(ii) Administrative tools by which records are created, stored, and retrieved, if not created or used as sources of information about organizations, policies, functions, decisions, or procedures of a naval activity. Normally, computer software, including source code, object code, and listings of source and object codes, regardless of medium are not agency records (that does not include the underlying data which is processed and produced by such software and which may in some instances be stored with the software). Exceptions to this position are outlined in § 701.3(b)(3).

(iii) Anything that is not a tangible or documentary record, such as an individual's memory or oral communication.

(iv) Personal records of an individual not subject to agency creation or retention requirements, created and maintained primarily for the convenience of an agency employee, and not distributed to other agency employees for their official use.

(v) Information stored within a computer for which there is no existing computer program for retrieval of the requested information.

(3) In some instances, computer software may have to be treated as a

agency record and processed under the FOIA. Such situations are rare and shall be treated on a case-by-case basis. Examples of when computer software may have to be treated as an agency record are:

(i) When the data is embedded within the software and cannot be extracted without the software. In that situation, both the data and the software must be reviewed for release or denial under FOIA.

(ii) Where the software itself reveals information about organizations, policies, functions, decisions, or procedures of a naval activity, such as computer models used to forecast budget outlays, calculate retirement system costs, or optimization models or travel costs.

Review exemptions (b)(4) and (b)(5) at § 701.26 and § 701.27 of subpart B of this part for guidance on release determinations of computer software.

(4) A record must exist and be in the possession and control of the Department of the Navy at the time of the request to be considered subject to this part and the FOIA. There is no obligation to create, compile, or obtain a record to satisfy a FOIA request.

(5) If unaltered publications and processed documents, such as regulations, manuals, maps, and related geophysical materials are available to the public through an established distribution system with or without charge, the provisions of 5 U.S.C. 552(a)(3) normally do not apply and they need not be processed under the FOIA. Normally, documents disclosed to the public by publication in the **Federal Register** also require no processing under the FOIA. In such cases, naval activities should direct the requester to the appropriate source to obtain the record.

(c) *Release authority.* Release authorities are commanding officers and heads of Navy and Marine Corps shore activities or their designee that are authorized to furnish copies of records under their cognizance for which no FOIA exemption applies.

(d) *Initial Denial Authority (IDA).* An official who has been granted authority to withhold records under FOIA, either in whole or in part, based on the FOIA exemptions. IDAs may also grant or deny requests for reduction or waiver of fees. See § 701.5 for a list of IDAs.

(e) *Appellate authority.* The Secretary of the Navy (SECNAV) has delegated his appellate authority to the Navy Judge Advocate General (NJAG) and the General Counsel (OGC) to rule on administrative appeals of denials of FOIA requests for information under their cognizance, as outlined in § 701.10.

(f) *Administrative appeal.* A request by a member of the general public, made under FOIA, asking the appellate authority to reverse the IDA's decision to withhold all or part of a requested record or to deny a request for waiver or reduction of fees. A requester may also file an administrative appeal for non-response to a FOIA request within the statutory time limits or for a "no record" response if he/she believes an adequate search was not conducted.

(g) *Public interest.* Public interest is official information that sheds light on a naval activity's performance of its statutory duties because it falls within the statutory purpose of FOIA in informing citizens about what their government is doing. That statutory purpose, however, is not fostered by disclosure of information about private citizens that is accumulated in various governmental files that reveals little or nothing about an agency's or official's own conduct.

(h) *Electronic data.* Electronic data are those records and information which are created, stored, and retrieved by electronic means. This does not include computer software, which is the tool by which to create, store, or retrieve electronic data.

(i) *Naval Nuclear Weapons Information (NNWI).* Information, classified or unclassified, which may be Restricted Data or Formerly Restricted Data, that relate to the production and utilization of nuclear weapons and/or nuclear weapon delivery systems. NNWI can be subdivided into three major categories:

(1) The production of nuclear weapons/delivery systems, such as research and development, design, manufacture, cost, testing, inventory, and arrangement of nuclear weapons/delivery systems.

(2) The utilization of nuclear weapons/delivery systems, such as operations, employment, command and control, training, administration, readiness and readiness inspections, allocations, stockpile, capabilities, transportation, logistics, storage, location, maintenance, and repair of nuclear weapons/delivery systems.

(3) Areas common to both nuclear weapons/delivery systems production and utilization, such as characteristics, effects, performance, vulnerabilities, reliability, safety, security (including physical security and administrative procedures), and accidents of nuclear weapon/delivery systems.

§ 701.4 Policy.

It is Department of the Navy policy to make its records available to requesters in accordance with FOIA. When requested, Navy and Marine Corps activities shall assist requesters in complying with the administrative requirements necessary to request materials sought under the Act.

(a) *Openness with the public.* The public has a right to information concerning the activities of its government. Department of the Navy policy is to conduct its activities in an open manner and to provide the public with a maximum amount of accurate and timely information concerning its activities, consistent always with the legitimate public and private interests of the American people. A Department of the Navy record requested by a member of the public who follows rules established by proper authority shall only be withheld when it is exempt from mandatory public disclosure based on one or more of the nine FOIA exemptions.

(b) *Avoidance of procedural obstacles.* Naval activities shall ensure that procedural matters do not unnecessarily impede a requester from obtaining Department of the Navy records promptly. Naval activities shall provide assistance to requesters to help them understand and comply with procedures established by this instruction. Fees shall not be used to discourage requesters (see subpart D of this part).

(c) *Prompt action on requests.* When a requester complies with the procedures established in this instruction for obtaining naval records, the request shall receive prompt attention. A reply shall be dispatched within 10 working days, unless a delay is authorized. If a naval activity has a significant number of requests (i.e., 10 or more), the requests shall be processed in order of receipt. This, however, does not preclude a naval activity from acting on a request which can be easily answered, regardless of its ranking within the order of receipt. A naval activity may also expedite action on a request regardless of its ranking within the order of receipt upon a showing of exceptional need or urgency. Exceptional need or urgency is determined at the discretion of the activity processing the request.

(d) *Use of exemptions/discretionary release.* Department of the Navy policy is to make records publicly available, unless they qualify for withholding under one or more of the nine FOIA exemptions (see subpart B of this part for an in-depth review of the exemptions). Naval activities may elect

to make a discretionary release. A discretionary release to one requester may, however, preclude the withholding of similar information under a FOIA exemption if subsequently requested by the same individual or someone else. Suggest the following language be included with the discretionary release of any record that could be subject to withholding:

> The information you requested is subject to being withheld under section (b) of the Freedom of Information Act. The release of this material to you by the Department of the Navy is discretionary and does not constitute a waiver of our right to claim this exemption for similar records in the future.

Additionally, a discretionary release is generally not appropriate for records exempt from disclosure under exemptions (b)(1)—classified; (b)(3)—exempted by statute; (b)(4)—trade secret/proprietary; (b)(6)—personal privacy; and (b)(7)(C)—personal information contained in investigatory records which if released would constitute an unwarranted invasion of privacy. Exemptions (b)(4), (b)(6), and (b)(7)(C) cannot be claimed for information which was supplied by the requester of the information.

(e) *Public domain.* Nonexempt records released under this instruction are considered in the public domain. Exempt records released under this instruction or other statutory or regulatory authority may be considered to be in the public domain only when their release constitutes a waiver of a FOIA exemption. When release does not constitute such a waiver, such as disclosure to a properly constituted advisory committee or a Congressional Committee, the released records do not lose their exempt status. Also, while authority may exist to disclose records to individuals in their official capacity, this instruction applies if the same individual seeks the records in a private or personal capacity.

(f) *Creating a record.* (1) A record must exist and be in the possession and control of the Department of the Navy at the time of the search to be considered subject to FOIA. Mere possession of a record does not presume departmental control; such records, or identifiable portions, should be referred to the originating activity for direct response to the requester. There is no obligation to create or compile a record to satisfy a FOIA request. A naval activity may, however, compile a new record if it is a more useful response to the requester, or less burdensome to the naval activity than providing existing records, and the requester does not object. The cost of creating or compiling such a record may not be charged to the requester unless the fee for creating the record is equal to or less than the fee which would be charged for providing the existing record. See subpart D of this part for fees.

(2) With respect to electronic data, the issue of whether records are actually or merely extracted from an existing database is not always readily apparent. Consequently, when responding to FOIA requests for electronic data where creation of a record, programming, or particular format are questionable, naval activities should apply a standard of reasonableness (i.e., if the capability exists to respond to a request, and the effort would be a "business as usual" approach, then the request should be processed; however, the request need not be processed when the capability to respond does not exist without a significant expenditure of resources, thus not being a normal "business as usual" approach). In such instances, the requester is advised that no record exists and the FOIA does not require agencies to create or compile a record to satisfy a FOIA request.

(g) *Reasonably segregable information.* FOIA requires that all "reasonably segregable" information must be released when the meaning of these portions is not distorted by deletion of the denied portions, and when it reasonably can be assumed that a skillful and knowledgeable person could not reasonably reconstruct the excised information. When a record is denied in whole, the response to the requester will specifically state that it is not reasonable to segregate portions of the record for release.

(h) *Special mail services.* Naval activities are authorized to use registered mail, certified mail, certificates of mailing, and return receipts. However, this use should be limited to instances where it appears advisable to establish proof of dispatch or receipt of FOIA correspondence.

(i) *Authentication of records released under FOIA.* In addition to the requirements of FOIA, records provided under FOIA shall be authenticated when necessary to fulfill an official governmental or other legal function. Authentication will be made with an appropriate seal. This service is not included in the FOIA fee schedule and naval activities may charge $5.20 for each authentication.

§ 701.5 Responsibility and authority.

(a) *Chief of Naval Operations (CNO).* CNO is designated as the official responsible for administering and supervising the execution of 5 U.S.C. 552 and Department of Defense Directives 5400.7 and 5400.7-R series, Department of Defense Freedom of Information Act Program (see 32 CFR part 286). CNO has designated the Assistant Vice Chief of Naval Operations (OP-09B30) as principal Department of the Navy FOIA Coordinator to:

(1) Set Department of the Navy policy on the provisions of the FOIA.

(2) Serve as principal advisor on all FOIA matters.

(3) Oversee the administration of the FOIA program, which includes preparing the Department of the Navy Annual FOIA Report for submission to Congress.

(4) Develop a Navy-wide FOIA training program and serve as training-oversight manager.

(5) Conduct staff assistance visits within the Department of the Navy to review compliance with 5 U.S.C. 552 and subparts A, B, C, and D of this part.

(6) Set Department of the Navy policy on the marking, handling, safeguarding and transmission of documents marked "For Official Use Only."

(b) *Commandant of the Marine Corps (CMC).* CMC is responsible for administering and supervising the execution of this instruction within the Marine Corps. The Commandant has designated the Director, Manpower Management Information Systems Division (HQMC (Code MI)) as the FOIA Coordinator for Headquarters, U.S. Marine Corps.

(c) *FOIA coordinator.* Each addressee is responsible for implementing and administering a FOIA program under this instruction. Each addressee shall designate a FOIA Coordinator to:

(1) Serve as principal point of contact on FOIA matters.

(2) Provide training for activity/command personnel on the provisions of 5 U.S.C. 552 and subparts A, B, C, and D of this part.

(3) Issue an implementing instruction which designates the activity's FOIA Coordinator and Initial Denial Authority(ies), provides guidance on the marking, handling, and safeguarding of documents marked FOUO, FOIA records disposition, and FOIA processing procedures.

(4) Review internal directives, practices, and procedures, including those for forms and records, for conformity with this instruction, when applicable.

(5) Compile input and submit consolidated Annual FOIA Report to Echelon 2 FOIA Coordinator, who, in turn, will provide consolidated report to CNO (OP-09B30).

(6) Review activity conformance with the marking, handling, transporting, and safeguarding of FOUO information.

(7) Provide guidance on handling FOIA requests and the scope of the FOIA exemptions.

(8) Review subpart C of this part and provide CNO (OP-09B30) with updated information, as appropriate.

(9) Conduct staff assistance visits within command and lower echelon commands to ensure compliance with FOIA.

(10) Echelon 2 FOIA Coordinators shall provide CNO (OP-09B30) with a complete listing of all FOIA Coordinators under their jurisdiction. Such information should include activity name and address, office code, name of FOIA Coordinator, and commercial and autovon telephone numbers.

(d) *Release Authorities.* (1) The role of the release authority is to respond to requests for documents under his/her cognizance for which no FOIA exemption applies. Release authorities are commanding officers and heads of all Navy and Marine Corps activities (departmental and field).

(2) Release authorities are required to coordinate with officials having cognizance over the subject matter of the requested record, if there is a question as to its releasability. However, if it is determined that a requested record requires withholding, in whole or in part, the release authority must refer the documents along with recommendations regarding release to the initial denial authority (IDA) in the chain of command. If geographically isolated, the release authority may forward the request to another IDA, if so authorized by the IDA in the chain of command.

(3) For records which are part of the Navy's Privacy Act (PA) systems of records, the record custodian specified in the systems notice is the appropriate authority to respond to the request.

(e) *Initial Denial Authorities (IDAs).* (1) The IDA role is to deny and grant requests, either in whole or in part, for documents or records under his or her cognizance; to grant one 10-working day formal extension to the time limit for responding to FOIA requests; and to deny requests to waive or reduce FOIA fees when the information sought relates to matters within their respective geographical areas of responsibility or chain of command.

(2) Within the Department of the Navy, the following chief officials, their respective vice commanders, deputies, and their principal assistants are designated as IDAs.

(i) Department of the Navy: Civilian Executive Assistants; CNO; CMC; Chief of Naval Personnel; Commanders of the Naval Systems Commands, Naval Intelligence Command, Naval Security Group Command, and Naval Computer and Telecommunications Command; Chief, Bureau of Medicine and Surgery; Auditor General of the Navy; Naval Inspector General; Director, Office of Civilian Personnel Management; Chief of Naval Education and Training; Commander, Naval Reserve Force; Chief of Naval Research; Commander, Naval Oceanography Command; heads of DON Staff Offices, Boards, and Councils; Flag Officers. NJAG and his Deputy, and the OGC and his Deputies, are excluded from this grant of authorization. While the NJAG and OGC are not Initial Denial Authorities, they are authorized to further delegate the authority conferred here to other senior officers/officials within NJAG and OGC.

(ii) Initial Denial Authorities may choose to delegate initial denial authority to those major activities under their control that receive voluminous requests. Such action is discretionary and should be limited.

(iii) For the shore establishment:

(A) All officers authorized under Article 22, Uniform Code of Military Justice (UCMJ), or designated in section 0120, Manual of the Judge Advocate General, to convene general courts-martial.

(B) Commander, Naval Investigative Service Command and Deputy Commander, Naval Legal Service Command.

(iv) In the Operating Forces: All officers authorized by Article 22, UCMJ, or designated in section 0120, Manual of the Judge Advocate General (JAGINST 5800.7C), to convene general courts-martial.

§ 701.6. Format and procedures for requesting information under FOIA.

(a) *Minimum requirements.* In an effort to eliminate any unnecessary burdens on members of the public, the Department of the Navy does not require requesters to complete a specific form to file a FOIA request. A request can be written or typed, but at a minimum should:

(1) Be in writing and indicate expressly, or clearly imply, that it is a request under 5 U.S.C. 552, Department of Defense Directives 5400.7 and 5400.7-R, Department of Defense Freedom of Information Act Program (see 32 CFR part 286), or subparts A, B, C, and D of this part. Verbal requests are not honored.

(2) Contain a reasonable description of the particular record(s) requested to enable naval personnel to locate or identify the particular record(s) desired with a reasonable amount of effort.

(3) Contain a clear statement of the requester's willingness to pay all fees or those up to a specified amount if the fees are expected to exceed the minimum fee waiver threshold, or provide satisfactory evidence that he or she is entitled to a waiver or reduction of such fees.

(b) *Identification of addressees.* To expedite processing of requests, requesters should submit written requests directly to the naval activity having cognizance over the records and clearly show all addressees within the Department of the Navy, Department of Defense, or other Federal agency to whom that or a similar request was also sent. That procedure will reduce processing time requirements and ensure better inter and intra-agency coordination. Naval activities are under no obligation to establish procedures to receive hand delivered requests.

(c) *Reasonably describe the record(s) being sought.* Identification of the record being sought is the responsibility of the requester. The requester must provide a description of the document that enables the Government to locate the record with a reasonable amount of effort. FOIA does not authorize "fishing expeditions." If a request does not contain a reasonable description, the naval activity shall advise the requester of the defect and when possible assist the requester in reframing the request. Naval activities are not obligated to act on the request until the requester responds with more specificity. When practical, naval activities shall assist the requester in identifying the records sought and in reformulating the request to reduce the burden on the agency in complying with FOIA.

(1) The following guidelines are provided for "fishing expedition" requests and are based on the principle of reasonable effort. Descriptive information about a record may be divided into two broad categories—file related and event related. File related includes information on the type of record (e.g., memorandum, letter, etc.), title, index citation, subject area, date the record was created, and originator. Event related includes the circumstances resulting in the record's creation or date and circumstances surrounding the event the record covers.

(2) Generally, a record is reasonably described when the description contains sufficient file related information to permit an organized non-random search of the activity's filing arrangements and existing retrieval systems, or when the record contains sufficient event related

information needed to conduct such a search.

(3) The following guidelines deal with requests for personal records. Ordinarily, when personal identifiers are provided only in connection with a request for records concerning the requester, only records retrievable by personal identifiers need be searched. Search for such records may be conducted under PA procedures (see subpart F of this part). No record may be denied that is releasable under FOIA.

(4) The previous guidelines notwithstanding, the decision of a naval activity concerning reasonableness of description must be based on knowledge of its files. If the description enables naval personnel to locate the record with reasonable effort, the description is adequate. However, if a naval activity receives a request not "reasonably described" it shall notify the requester of the defect and provide guidance on specificity required to begin a search.

(d) *Fees.* (1) Fees may not be used to discourage requesters. If fees are expected to exceed the minimum fee waiver threshold of $15.00, the requester is required to address fees in the request, i.e., a willingness to pay all fees or those up to a specified amount, or request a waiver/reduction of fees.

(2) To assist naval activities in determining assessable fees, requesters are encouraged to identify the fee category for which they wish to be considered. If the requester believes he/she qualifies for a waiver/reduction of fees, requesters are required to provide specific justification regarding qualification for a waiver so that decision can be rendered. See Subpart D of this Part 701 for further information on fees.

(e) *Treatment of requests which do not meet the minimum requirements.* (1) In those instances when a request does not meet the minimum requirements, naval activities should nonetheless return the requests within 10 working days and advise the requester of how to perfect the request. Naval activities may contact the requester by telephone to refine the request. For example, if a requester has failed to "reasonably describe" the records being sought, he/she may be asked to provide identifying data such as location, timeframe, originator, background information, etc., to enable a search. If the requester has failed to mention fees and fees are applicable, the requester should be provided an estimate of the cost involved in processing the request. When practicable, naval activities are encouraged to contact requesters to clarify what they are seeking.

(2) If a request fails to qualify within this instruction but the requested record is available and releasable in its entirety, the responding official may provide a copy of the record if he or she determines it to be in the best interest of the activity. This provision is within the sole and exclusive discretion of the responsible official of the activity concerned and does not create an exception to or grounds for waiver of the minimum requirements.

§ 701.7 Procedures for processing FOIA requests.

(a) *Control system.* All requests for records which cite or imply the FOIA must be entered into a formal control system, either manual or computerized, that is designed to track the request from receipt to response. Information contained in the tracking system should at a minimum include the name of the requester, the date of the request, the date the request was received, suspense date, and the date the response was made. This will ensure that the requester is apprised of the status of his/her request within 10 working days and will provide required information should the requester challenge the processing of his/her request.

(1) *Receipt controls.* At a minimum, date stamp the request upon receipt, establish a suspense control record and follow-up procedures, and conspicuously stamp or label the request "FREEDOM OF INFORMATION ACT REQUEST" to indicate priority handling throughout processing. Naval activities are encouraged to assign a FOIA Case Number for each request and to apprise the requester of the number assigned. This number is an effective tool for tracking, filing, and retrieving the request.

(2) *Forwarding controls.* As a rule, requests forwarded to another activity for action should have the letter of referral and envelope conspicuously stamped or labeled "FREEDOM OF INFORMATION ACT REQUEST" and a record shall be kept of the request, and the date and activity to which it was forwarded.

(b) *Time limits.* Once a request has been received by a naval activity having cognizance over the requested record(s), that activity has 10 working days (excluding Saturdays, Sundays, and legal holidays) to issue a letter which advises the requester of the action to be taken on the request (i.e., documents are denied; documents are released; documents will be released within a specific timeframe). If a naval activity is unable to comply with the request within the 10 working day timeframe, then a formal or informal time extension must be pursued and a letter forwarded to the requester advising of the extension.

(1) A formal time extension letter is issued in those instances where an activity requires up to an additional 10 working days to respond to a request because of the need to:

(i) *Search.* The need to search for and collect records located in whole or part at places separate from the activity processing the request;

(ii) *Examine.* The need to search for, collect, and examine a substantial number of records responsive to a request; or,

(iii) *Consult.* The need to consult with another naval activity or federal agency with a substantial interest in the determination of the request.

(2) A formal time extension response must be issued by the IDA within 10 working days of receipt of the request, describe the circumstance(s) for the delay, and indicate the anticipated date for a substantive response.

(3) In those instances where it appears the request might be ultimately denied, in whole or in part, the appellate authority (i.e., NJAG or OGC) may be consulted by expeditious means prior to authorizing a formal extension.

(4) In those instances when it is anticipated the normal statutory time limits (including the statutory time extension) are insufficient to provide a response, the IDA shall acknowledge the request in writing prior to the expiration of the normal statutory time limits (including the statutory time extension), describe the circumstance(s) requiring the delay and indicate the anticipated date for the substantive response. The requester shall be advised that an appeal may be made to the cognizant appellate authority within 60 calendar days or await a substantive determination by a specified date. It shall be made clear that such an agreement does not prejudice the right of the requester to appeal an adverse substantive determination.

(5) In those unusual cases where the statutory time limits cannot be met and no informal extension has been agreed to, the inability to process any part of the request within the specified time should be explained to the requester, with notification that the delay may be treated as an initial denial with a right to appeal, or that the requester may agree to await a substantive response by an anticipated date. It should be made clear that any such agreement does not prejudice the right of the requester to appeal the initial decision after it is made. Further, naval activities should be advised that the requester still

retains the right to treat this delay as a defacto denial with full administrative remedies.

(6) Informal extension of time limits—a recommended alternative is to negotiate an informal extension of time with the requester. The advantages include the ability to agree on a mutually acceptable date to respond that exceeds 10 working days, and the letter of confirmation does not require the signature of an IDA. Additionally, it does not impact on the additional days the appellate authority may take when responding to an appeal.

(c) *Decision to release records.* Release authorities may release records under their cognizance which do not qualify for denial under FOIA exemptions. Such responses should be made within the applicable time limits of FOIA and should be processed as follows:

(1) If the requested records are releasable in their entirety, release authorities should forward the records to the requester and advise of any applicable fees.

(2) If the requested records are releasable in their entirety but not yet available, the release authority should notify the requester the request has been approved and the requested records will be forwarded by a specified date.

(3) If the request for examination of records is approved, notify the requester of the time and place.

(d) *Processing documents originated by/created for another activity.* (1) If an official receives a request for records that he or she holds, but which were originated by another naval activity, the official shall normally coordinate with that activity prior to referring the FOIA request and copies of the requested documents to the originator for direct response. The naval activity that initially received the request is responsible for notifying the requester of the referral. The originating naval activity shall not release or deny such records without prior consultation with the referring naval activity.

(2) If an official receives a request for records that he or she holds, but were created for another naval activity or government agency, the official shall refer the FOIA request and copies of the requested documents to that activity/agency for direct response, after coordination and concurrence. The activity/agency may have an equally valid interest in withholding the record as the naval activity that created it. In such referrals, the naval activity should provide a recommendation concerning release with the referral. The naval activity that initially received the request is responsible for notifying the requester of the referral.

(e) *Processing misdirected requests.* Requesters are not always aware of the correct activity to address a FOIA request.

(1) A request received by a naval activity having no records responsive to the request shall only be referred to another naval activity if the activity contacts the naval activity and confirms its cognizance over the requested information. When a member of the public complies with the procedures established in this instruction for obtaining records, the request shall receive prompt attention and a reply dispatched within 10 working days, unless a delay is authorized. Each naval activity is responsible for developing procedures to ensure the expeditious handling, prompt retrieval, and review of requested records. The 10 working day time limit commences upon receipt of the request by the cognizant activity.

(2) If the cognizant official is unable to respond to the requester within the statutory time limit, he or she may seek a formal or informal extension of time.

(3) If a naval activity has a significant number of requests (e.g., 10 or more), the requests generally will be processed in order of receipt. But a naval activity may commence action on an easily answered request, regardless of its ranking within the order of receipt.

(f) *Decision to deny records in whole or in part.* To deny a requested record that is in the possession and control of the Department of the Navy, it must be determined that the record is included in one or more of the nine categories of records exempt from mandatory disclosure as provided by the FOIA and addressed at subpart B of this part.

(1) Because release authorities cannot deny information, they must forward responsive documents along with their release determination to an IDA for consideration and response to the requester. In those instances, the release authority will apprise the requester that his/her request and responsive documents were referred to the activity having cognizance over the documents for a release determination and direct response to the requester. The referral to an IDA shall include a copy of the request, documents responsive to the request, recommendation on partial/total denial, and supporting rationale for the exemption(s) claimed.

(2) When an IDA receives a referral from a subordinate activity recommending a FOIA request be denied in whole or in part, or receives a FOIA request for documents under his/her cognizance, the IDA shall take one of the following actions within 10 working days:

(i) Deny or release the requested information. If an IDA determines the record contains information which is not releasable under FOIA, and any releasable information contained in the record is not reasonably segregable from the non-releasable information, notify the requester of the exemption(s) claimed and provide procedures to be followed should the requester decide to appeal the determination to appellate authority.

(ii) If unable to respond within the applicable time limits, explain the reason(s) for the delay to the requester, with notification that he or she may treat this delay as an initial denial with a right to submit an administrative appeal to the cognizant appellate authority, or that the requester may agree to await a substantive determination by a specified date. It shall be made clear that any such agreement does not prejudice the right of the requester to appeal an adverse substantive determination.

(iii) If an IDA determines that the requester's claimed entitlement to waiver/reduction of fees is not warranted, IDAs shall notify the requester of such determination, provide the reason(s) for the denial, and advise the requester of the right to appeal the determination to the cognizant appellate authority within 60 calendar days. If the requester appeals the denial to waive/reduce fees, the release of the records may be withheld until the fee is paid or the appellate authority grants a waiver/reduction of fees.

(3) IDAs are responsible for maintaining copies of initial denials in a form suitable for rapid retrieval, periodic statistical compilation, and management evaluation.

(g) *Excising documents.* (1) *Classified documents.* Since FOIA requires that all reasonably segregable portions of documents be released to the requester, there will be instances when portions of documents which contain classified markings are subject to release. In these instances, naval activities shall cross through the classified markings that appear at the top and bottom of the document and cross through any classified paragraph markings that are being released. This practice is necessary to eliminate any appearance that a "classified" document was released.

(2) *Unclassified documents.* Naval activities are encouraged to "blank out" and bracket the denied information and annotate the exemption(s) claimed. This practice will permit the requester to

easily identify information being withheld and the basis for withholding.

(h) *"Other Reasons" for not releasing a record.* Besides denying a records in whole or in part, there are six "other reasons" for not releasing a record. In most instances, these "other reason" responses do not constitute a denial of information and therefore do not require the signature of an IDA. They are:

(1) *Transferred request.* Requester advised that his/her request and/ or requested documents have been transferred to another naval activity or federal agency having cognizance over the requested information for action and direct response.

(2) *Lack of records.* Requester advised that a search of files held by the naval activity has resulted in a failure to locate any responsive records. Such response now requires that a requester be advised of his/her right to appeal the adequacy of the search to the cognizant appellate authority. The response does not normally require the signature of an IDA.

(3) *Failure of requester to reasonably describe records being sought.* Requester advised that his/her request requires specificity with regard to description of the records being sought to enable the naval activity to conduct a reasonable search. Such responses generally apprise the requester of the kind of specificity required.

(4) *Other failures by requester to comply with published rules and/or directives.* Requester advised that he/ she has failed to comply with established rules/directives, such as failure to agree to pay fees, and therefore the request is being returned for refinement.

(5) *Withdrawal.* Requester contacted the naval activity by telephone or letter and advised he/she wishes to cancel the request or appeal.

(6) *Not an agency record.* Requester advised the information/records he/she seeks is not an agency record as defined by § 701.3 of Subpart A.

(i) *Consultation/coordination.* The Department of the Navy processes thousands of FOIA requests annually. Because there is no central repository for records and no central release/ denial authority, proposed responses shall be properly coordinated and appropriate officials consulted prior to a response being made to the requester. Specifically:

(1) Naval activities and federal agencies with a substantial interest in the subject matter of the requested records should be consulted prior to release or denial of information.

(2) Public affairs officers or the Chief of Information (CHINFO) should be consulted when a FOIA request is received from a news media representative, the records requested are considered newsworthy, or a denial of a request is expected to be publicly challenged. CHINFO should be promptly notified of any release having evident public affairs implications and a copy of the request and response should be provided.

(3) The appropriate JAG attorney or field counsel should be consulted on the interpretation and application of this instruction where a denial of a request is expected to be judicially challenged.

(j) *Response to the requester.* (1) Initial determinations to release or deny a record normally shall be made and the decision reported to the requester within 10 working days after receipt of the request by the official designated to respond. When the time for response becomes an issue, the official responsible for replying shall acknowledge to the requester the date of the receipt of the request.

(2) When a decision is made to release a record, a copy should be made available promptly to the requester once he or she has complied with preliminary procedural requirements.

(3) When a request for a record is denied in whole or in part, the official designated to respond shall inform the requester in writing of the IDA's name, rank, and title, shall cite the specific exemption(s) that apply in sufficient detail, and provide the requester with the name and address of the appellate authority, should the requester desire to file an appeal. When claiming exemption "(b)(1)," IDAs shall to the extent reasonably feasible, provide the requester with a summary of the applicable criteria for classification. Additionally, the marking "For Official Use Only" on a requested document does not constitute a basis for denial. Rather, it alerts the reviewer that the document may contain information which is protectible under exemptions (b)(2) through (b)(9). It is up to the reviewing official to advise the requester of the applicable exemptions and to release all "reasonably segregable" information.

(k) *Fees.* The final response to the requester should contain information on the fee status of the request. Generally, information shall reflect one or more of the following conditions:

(1) "The fees for processing your request total $. Please forward your check or money order made payable to the Treasurer of the United States to this office within 30 days." Subpart D of this part addresses when fees may be collected in advance of forwarding the documents.

(2) All fees have been received.

(3) Fees have been waived because they fall below the automatic fee waiver threshold.

(4) A request for waiver/reduction of fees has been denied.

(5) Fees have been waived or reduced from a specified amount to another specified amount because the rationale provided in support of a request for waiver has been accepted.

(6) Fees due in a specified amount have not been received (see subpart D of this part for specific information on FOIA fees and fee rates for technical data).

§ 701.8 Records requiring special handling.

The following actions shall be taken on requests for:

(a) *Classified records.* (1) If a naval activity receives a request for information whose existence or nonexistence is itself classifiable under Executive Order 12356. 50 U.S.C. 401, the naval activity shall refuse to confirm or deny the existence or nonexistence of the requested information.

(2) If a naval activity receives a request for documents in its custody that were classified by another agency, or which contains information classified by another agency, it shall refer the request and copies of the requested documents to the originating agency for processing, and may, after consultation with the originating agency inform the requester of the referral. Referred records shall be identified consistent with security requirements. In cases where the originating agency determines they can neither confirm nor deny the existence or nonexistence of the requested information, the referring agency shall deny the request.

(3) If a naval activity receives a request for classified records or information originated by another naval activity, for which the head of the activity is not the classifying authority under OPNAV Instruction 5520.1 series, "Department of the Navy Information and Personnel Security Program Regulation," the request, copies of the requested documents, and a recommendation concerning release (if appropriate) shall promptly be readdressed and forwarded to the official having classification authority for the subject matter. That official will make a release determination concerning the classified information and notify the requester, or the activity originally receiving the request, in 10 working days of that determination. The naval activity that initially received the request has responsibility for notifying

the requester of the referral. Referred records shall only be identified to the extent consistent with security requirements.

(b) *Naval Investigative Service (NIS) reports.* The Commander, Naval Investigative Service Command (COMNISCOM) is the release/denial authority for all NIS reports. Accordingly, a request for a NIS report shall be promptly readdressed and forwarded to COMNISCOM and the requester notified of the referral. Direct liaison with COMNISCOM prior to the referral is encouraged.

(c) *Naval Inspector General reports.* (1) The Naval Inspector General (NAVINSGEN) is the release/denial authority for all investigations and inspections conducted by or at the direction of NAVINSGEN and for any records held by any command that relate to Navy hotline complaints that have been referred to the NAVINSGEN. Accordingly, such requests shall be promptly readdressed and forwarded to NAVINSGEN and the requester notified of the referral. Requests for local command Inspector General reports which have not been referred to the NAVINSGEN may be released by the local command.

(2) The Deputy Naval Inspector General for Marine Corps Matters (DNIGMC) is the release authority for all investigations conducted by the DNIGMC. Requests for local Marine Corps command Inspector General reports shall be coordinated with the DNIGMC.

(d) *Manual of the Judge Advocate General (JAGMAN) investigative reports and courts-martial records.* NJAG is the release/denial authority for all JAGMAN investigative reports and courts-martial records. Requests for JAGMAN investigative reports and courts-martial records shall be promptly readdressed and forwarded to NJAG and the requester notified of the referral.

(e) *Mishap Investigation Reports (MIRs).* The Commander, Naval Safety Center (COMNAVSAFECEN) is the release/denial authority for all requests for mishap investigation reports. Requests for mishap investigation reports shall be promptly readdressed and forwarded to COMNAVSAFECEN and the requester notified of the referral.

(f) *Naval Audit Service reports.* The Auditor General of the Navy is the release/denial authority for all Naval Audit Service reports. Requests for audit reports shall be promptly readdressed and forwarded to the Auditor General and the requester notified of the referral.

(g) *Technical documents controlled by distribution statements.* A request for a technical document to which "Distribution Statement B, C, D, E, F, or X" (see OPNAVINST 5510.1 series) is affixed shall be promptly readdressed and forwarded to the "controlling DOD office" for review and release determination. The naval activity that initially received the request is responsible for notifying the requester of the referral. Direct liaison with the cognizant official prior to referral is encouraged.

(h) *Records originated by other government agencies.* When a request for records originated by an agency outside the Department of the Navy is received, promptly readdress and forward the request along with copies of the requested documents to the cognizant agency and notify the requester of the referral. That may be accomplished by sending a copy of the referral letter, less attachments, to the requester. The 10 working day time limit begins when the request is received by the cognizant agency. If additional guidance is required, contact CNO (OP-09B30) or CMC (Code MI-3), as appropriate. Direct liaison with the cognizant agency is encouraged to ensure expeditious handling of the request.

(i) *National Security Council (NSC)/ White House Documents.* The Director, NSC is the release/denial authority for NSC documents or White House files. Requesters seeking NSC or White House documents should be notified to write directly to the NSC or White House for such documents. Department of the Navy documents in which NSC or the White House has a concurrent reviewing interest shall be forwarded to the Office of the Assistant Secretary of Defense (Public Affairs) (OASD(PA)), ATTN: Directorate for Freedom of Information and Security Review (DFOISR), which shall effect coordination with the NSC or White House, and return the documents to the originating activity after review and a release determination is made. NSC or White House documents discovered in a naval activity's files which are responsive to a FOIA request shall be forwarded to the Director, Freedom of Information and Security Review, OASD(PA), for subsequent coordination with the NSC or White House and returned to the naval activity for a release determination. Additionally, in such instances an information copy should be provided to CNO (OP-09B30).

(j) *Naval Telecommunications Procedures (NTP) publications.* The Commander, Naval Computer and Telecommunications Command (COMNAVCOMTELCOM) is the release/denial authority for NTP publications. Requests for NTP publications shall be promptly readdressed and forwarded to COMNAVCOMTELCOM and the requester notified of the referral. Direct liaison with COMNAVCOMTELCOM prior to referral is encouraged.

(k) *Naval Nuclear Weapons Information (NNWI).* The release/denial of requests for NNWI require special handling:

(1) *Release of NNWI.* Naval activities identifying NNWI which they believe qualifies for release, shall forward the request, responsive documents, and supporting rationale to the CNO (OP-09B30) who will coordinate with appropriate Navy staffs and OASD(PA) regarding release.

(2) *Denial of NNWI.* Naval activities identifying NNWI which qualifies for denial under one or more FOIA exemptions shall forward the request, responsive documents, and supporting rationale to the IDA having cognizance over the requested information.

(3) *No Record Response.* Naval activities receiving requests for NNWI where no records are found shall respond directly to the requester (the definition of NNWI appears at Subpart A, § 701.3).

(l) *Naval Nuclear Propulsion Information (NNPI).* The Director, Naval Nuclear Propulsion Program (OP-OON/ NAVSEA 08) is the release/denial authority for all information concerning NNPI. Naval activities receiving such requests are responsible for searching their files for responsive records. If no documents are located, the naval activity should respond to the requester and provide OP-OON with a copy of the request and response. If documents are located, the request, responsive documents, and a recommendation regarding release should be promptly readdressed to the CNO (OP-OON/ NAVSEA 08) who will ensure proper coordination and review. If information is deemed releasable, in whole or in part, CNO (OP-00N/NAVSEA 08) will forward it to OASD(PA) for staffing through Defense activities prior to release to the requester. Denials need not be processed through OASD(PA).

(m) *Medical quality assurance documents.* The Chief, Bureau of Medicine and Surgery (BUMED) is the release/denial authority for all naval medical quality assurance documents as defined by Title 10, United States Code, Section 1102. Requests for medical quality assurance shall be promptly readdressed and forwarded to BUMED and the requester notified of the referral.

(n) *Records of a non-U.S. Government source.* (1) When a request is received for a record that was obtained from a

non-U.S. Government source, or for a record containing information clearly identified as provided by a non-U.S. Government source, the source of the record or information (known as "the submitter" for proprietary data under FOIA exemption (b)(4)) shall be promptly notified of the request and afforded reasonable time (e.g., 30 calendar days) to present any objections concerning release, unless it is clear that there can be no valid basis for objection. That practice is required for FOIA requests for data not deemed clearly exempt from disclosure under exemption (b)(4). If, for example, the record or information was provided with actual or presumptive knowledge of the non-U.S. Government source and established that it would be made available to the public upon request, there is no obligation to notify the source. Any objections shall be evaluated. The final decision to disclose information claimed to be exempt under exemption (b)(4) shall be made by an official equivalent in rank to the official who would make the decision to withhold that information under FOIA. When a substantial issue has been raised, the naval activity may seek additional information from the source of the information and afford the source and requester reasonable opportunities to present their arguments on legal and substantive issues prior to making an agency determination. When the source advises he or she will seek a restraining order or take court action to prevent release of the record or information, the requester shall be notified and action on the request normally shall not be taken until after the outcome of that court action is known. When the requester brings court action to compel disclosure, the submitter shall be promptly notified of this action.

(2) The coordination provisions of this paragraph also apply to any non-U.S. Government record in the possession and control of the Department of the Navy from multinational organizations, such as the North Atlantic Treaty Organization (NATO) and North American Air Defense (NORAD), or foreign governments. Coordination with foreign governments will be made through the Department of State.

(o) *Government Accounting Office (GAO) documents.* On occasion, the Department of the Navy receives FOIA requests for GAO documents containing Department of the Navy information, either directly from requesters, or as referrals from the GAO. Since the GAO is outside the Executive Branch and therefore not subject to FOIA, all FOIA requests for GAO documents containing Department of the Navy information will be processed by the Department of the Navy. In those instances when a requester seeks a copy of an unclassified GAO report, naval activities may apprise the requester of its availability from the Director, GAO Distribution Center, ATTN: DHISF, P.O. Box 6015, Gaithersburg, MD 20877-1450 under their cash sales program.

(p) *Mailing lists.* Frequent FOIA requests are received for mailing lists of the home addresses and/or duty station addresses of naval personnel.

(1) A list of home addresses is not releasable without the individuals' consent because it is a clearly unwarranted invasion of the individuals' personal privacy, and therefore, may be withheld from disclosure under 5 U.S.C. 552(b)(6), see subpart B of this part.

(2) Unclassified information about service members may be withheld when disclosure "would constitute a clearly unwarranted invasion of personal privacy" under FOIA (exemption (b)(6) applies). Disclosure of lists of names and duty addresses or duty telephone numbers of members assigned to units that are stationed in foreign territories, routinely deployable, or sensitive, constitutes a clearly unwarranted invasion of personal privacy. Disclosure of such information poses a security threat to those service members because it reveals information about their degree of involvement in military actions in support of national policy, the type of naval unit to which they are attached, and their presence or absence from their households. Release of such information aids the targeting of service members and their families by terrorists or other persons opposed to implementation of national policy. Only an extraordinary public interest in disclosure of this information can outweigh the need and responsibility of the Navy to protect the tranquility and safety of service members and their families who repeatedly have been subjected to harassment, threats, and physical injury. Units covered by this policy are:

(i) Those units located outside the 50 states, District of Columbia, Commonwealth of Puerto Rico, Guam, U.S. Virgin Islands, and American Samoa.

(ii) Routinely deployable units. Those units that normally deploy from homeport or permanent station on a periodic or rotating basis to meet operational requirements or participate in scheduled exercises. This includes routinely deployable ships, aviation squadrons, operational staffs, and all units of the Fleet Marine Force (FMF). Routinely deployable units do not include ships undergoing extensive yard work or whose primary mission is support of training, e.g., yard craft and auxiliary aircraft landing training ships.

(iii) Units engaged in sensitive operations. Those units primarily involved in training for or conduct of covert, clandestine, or classified missions, including units primarily involved in collecting, handling, disposing, or storing of classified information and materials. This also includes units engaged in training or advising foreign personnel. Examples of units covered by this exemption are nuclear power training facilities, SEAL Teams, Security Group Commands, Weapons Stations, and Communication Stations.

(3) Except as otherwise provided, lists containing names and duty addresses of DOD personnel, both military and civilian, who are assigned to units in the Continental United States (CONUS) and U.S. territories shall be released regardless of who has initiated the request.

(4) Exceptions to this policy must be coordinated with the CNO (OP-09B30) or CMC (MI-3) prior to responding to requests, including those from Members of Congress. The foregoing policy should be considered when weighing the releasability of the address or phone number of a specifically named individual.

§ 701.9 For Official Use Only (FOUO).

FOUO is a marking which is placed on documents to alert the holder that they contain information that may be withheld under exemptions (b)(2) through (b)(9) of the FOIA. Because FOUO is not a security classification, exemption (b)(1) does not apply.

(a) *Prior FOUO application.* The prior application of FOUO is not a conclusive basis for withholding a record requested under FOIA. When such a record is requested, it shall be evaluated to determine whether FOIA exemptions apply in withholding all or portions of the record. Information which is reasonably segregable and does not fall under a FOIA exemption(s) must be released to the requester.

(b) *Historical papers.* Records such as notes, working papers, and drafts retained as historical evidence of Department of the Navy actions have no special status apart from FOIA exemptions.

(c) *Time to mark records.* The marking of records at the time of their creation provides notice of FOUO content and facilitates review when a record is requested under the FOIA. Records requested under FOIA that do not bear

such markings, shall not be assumed to be releasable without examination for the presence of information that requires continued protection and qualifies as exempt from public release.

(d) *Distribution statement.* Information in a technical document that requires a distribution statement under OPNAVINST 5510.1 series, "Department of the Navy Information and Personnel Security Program Regulation," shall bear that statement and may be marked FOUO, as appropriate.

(e) *Location of markings.* (1) An unclassified document that contains FOUO information shall have FOR OFFICIAL USE ONLY typed, stamped, or printed in capital letters centered at the bottom on the outside of the front cover (if any), on each page containing FOUO information, and on the outside of the back cover (if any).

(2) An unclassified directive that contains FOUO information shall have FOR OFFICIAL USE ONLY typed, stamped, or printed in capital letters centered at the bottom on the outside of the front cover (if any), on each page of the directive top and bottom, and on the outside of the back cover (if any).

(3) Within a classified document, an individual page that contains both FOUO and classified information shall be marked at the top and bottom with the highest security classification of information appearing on the page.

(4) Within a classified or unclassified document, an individual page that contains FOUO information, but does not contain classified information, shall have FOR OFFICIAL USE ONLY typed, stamped, or printed in capital letters centered at the top and bottom edge of the page.

(5) Other records, such as photographs, films, cassette tapes, movies, or slides, shall be marked FOR OFFICIAL USE ONLY so that a recipient or viewer knows the status of the information.

(6) Unclassified automatic data processing (ADP) media with FOUO information shall be marked as follows:

(i) An unclassified deck of punched or aperture cards with FOUO information shall be marked as a single document with FOR OFFICIAL USE ONLY marked on the face of the first and last card, and on the top of the deck.

(ii) An unclassified magnetic tape, cassette, or disk pack that contains FOUO information shall have FOR OFFICIAL USE ONLY marked externally on a removable label. The resulting hard copy report or computer printout shall reflect the FOR OFFICIAL USE ONLY marking on the top and bottom of each page. It may be accomplished by using a programmable header or marking the hard copy manually.

(7) FOUO material transmitted outside the Department of the Navy requires an expanded marking to explain the significance of the FOUO marking. This may be accomplished by typing or stamping the following statement on the record prior to transfer: "This document contains information EXEMPT FROM MANDATORY DISCLOSURE under the FOIA. Exemption(s)...apply(ies)."

(f) *Release and transmission procedures.* Until FOUO status is terminated, the following release and transmission instructions apply:

(1) FOUO information may be disseminated within Department of the Navy activities and between officials of the Department of the Navy and contractors and grantees who conduct official business for the Department of the Navy or Department of Defense. Recipients shall be made aware of the status of such information, and transmission shall be by means that preclude unauthorized public disclosure. Transmittal documents shall call attention to the presence of FOUO attachments.

(2) Department of the Navy holders of FOUO information may convey such information to officials in other departments or agencies of the executive and judicial branches to fulfill a governmental function, subject to any limitations contained in the Privacy Act (PA) (see Subpart F of this Part 701), pertaining to disclosure of personal information from PA record systems. When transmitting these records, ensure they are marked FOR OFFICIAL USE ONLY, and the recipient is advised the information has been exempt from public disclosure under FOIA and that special handling instructions do or do not apply. For purposes of disclosing records, Department of Defense is the "agency."

(3) Records released to Congress or the GAO should be reviewed to see if the information warrants FOUO status. If not, prior FOUO markings shall be removed. If the withholding criteria are met, the records shall be marked FOUO and the recipient provided an explanation for such exemption and marking. Alternatively, the recipient may be requested, without marking the record, to protect it against public disclosure for reasons that are explained.

(4) Each part of electronically transmitted messages containing FOUO information shall be marked appropriately. Unclassified messages containing FOUO information shall contain the abbreviation "FOUO" before the beginning of the text. Such messages shall be transmitted per communications security procedures in ACP-121 (United States Supplement 1, "Communication Instructions") for FOUO information.

(g) *Transporting FOUO information.* Records which contain FOUO information shall be transported in a manner that precludes disclosure of contents. If not commingled with classified information, FOUO information may be sent via first-class mail or parcel post. Bulky shipments that otherwise qualify under postal regulations may be sent fourth-class mail.

(h) *Safeguarding FOUO information.* (1) During normal working hours, records determined to be FOUO shall be placed in an out-of-sight location if the work area is accessible to non-governmental personnel.

(2) At the close of business, FOUO records shall be stored to preclude unauthorized access. Filing such material with other unclassified records in unlocked files, desks, or similar containers is adequate when U.S. Government or government contractor internal building security is provided during non-duty hours. When internal security control is not exercised, locked buildings or rooms normally provide adequate after-hours protection. If such protection is not considered adequate, FOUO material shall be stored in locked receptacles, such as file cabinets, desks, or bookcases. FOUO records that are subject to the provisions of the PA (see Subpart F of this Part 701) shall meet the safeguards for that group of records as outlined in the PA systems notice.

(3) Guidance for safeguarding media marked FOUO and processed by an ADP system, activity, or network is addressed in OPNAVINST 5239.1 series, "Department of the Navy Automatic Data Processing Security Program."

(i) *Termination.* The originator or other competent authority, such as an IDA or appellate authority, will terminate FOUO markings or status when the information no longer requires protection from public disclosure. When FOUO status is terminated, all known holders shall be notified as practical. Upon notification, holders shall remove the FOUO markings. Records in file or storage need not be retrieved solely for that purpose.

(j) *Disposal.* (1) Non-record copies of FOUO material (including hard copy reports and computer printouts) may be destroyed by tearing each copy into pieces to preclude reconstructing, and disposed in regular trash containers. When local circumstances or experience

indicates that this destruction method is insufficient, local authorities may direct other methods while considering the additional expense balanced against the sensitivity of FOUO information in the records. FOUO information on unclassified magnetic storage media shall be disposed of by overwriting the media one time with any one character. Storage areas within an ADP system (internal memory, buffers, registers, and similar storage areas) may be cleared by using a hardware clear switch, a power-on reset cycle, or a program designated to overwrite the storage area.

(2) Record copies of FOUO documents shall be disposed of following the disposal standards established under the Records Disposal Manual for the particular kind of record.

(k) *Unauthorized disclosure.* The unauthorized disclosure of FOUO records does not constitute an unauthorized disclosure of Department of the Navy information classified for security purposes. However, appropriate administrative or disciplinary action shall be taken against those responsible. Unauthorized disclosure of FOUO information that is protected by the PA may result in civil and criminal sanctions against responsible person(s). The naval activity that originated the FOUO information shall be informed of its unauthorized disclosure.

§ 701.10 FOIA appeals/judicial actions.

(a) *How to file an appeal.* The following guidelines should be followed by individuals wishing to appeal a denial of information, a request for waiver/reduction of fees, or a "no record" response:

(1) The appeal must be received by the cognizant appellate authority (i.e., NJAG or OGC) within 60 days of the date of the response.

(2) The appeal letter must be in writing and requesters should provide a copy of the IDA's response when filing a written appeal to the Navy's appellate authorities (OGC or NJAG, depending on subject matter), regarding an IDA's decision that a record is exempt in whole or in part or because a naval activity denied a request for a waiver/reduction of fees. The requester should include a copy of the denial letter and provide supporting rationale on why the appeal should be granted. The requester may appeal a "no records" response if he/she believes an adequate search of files was not conducted.

(b) *Time of receipt.* The time limits for responding to a FOIA appeal commence when the appeal reaches the office of the appellate authority having jurisdiction over the record. Misdirected appeals should be referred expeditiously to the proper appellate authority.

(c) *Appellate authorities.* (1) Responsibility and authority. NJAG and OGC are authorized to adjudicate appeals made to the Secretary of the Navy (SECNAV) on denials of requests for copies of Department of the Navy records or portions thereof, or refusals to waive or reduce fees on matters within their respective areas of cognizance. That includes the authority to release or withhold records, or portions thereof, waive or reduce fees, and to act as required by SECNAV for appeals under 5 U.S.C. 552 and subparts A, B, C, and D of this part. NJAG and OGC are further authorized to delegate this authority to a designated Assistant NJAG and the Principal Deputy OGC, respectively, under such terms and conditions as they may deem appropriate.

(2) Respective areas of cognizance. As delineated in SECNAV Instructions 5430.25D and 5430.27A (NOTAL), the respective areas of cognizance of NJAG and OGC for providing legal services for the Department of the Navy are:

(i) NJAG. In addition to military law, all matters except those falling under the cognizance of OGC.

(ii) OGC. Business and commercial law aspects of:

(A) Acquisition, custody, management, transportation, taxation, and disposition of real and personal property and the procurement of services, including the fiscal, budgetary, and accounting aspects thereof; excepting, however, tort claims and admiralty claims arising independently of contracts, and matters relating to the naval petroleum reserves;

(B) Operations of the Military Sealift Command, excepting tort and admiralty claims arising independently of contracts;

(C) Office of the Comptroller of the Navy;

(D) Naval Computer and Telecommunications Command;

(E) Patents, inventions, trademarks, copyrights, royalty payments, and similar matters;

(F) Procurement of foreign military sales, co-production and cooperative research and development and related agreements, NATO standardization agreements, and matters relating to the Arms Exports Control Act;

(G) Department of the Navy litigation before the Armed Services Board of Contract Appeals; and,

(H) Civilian personnel law matters on employing present and former Navy civilian employees.

(d) *Addresses for appeals.* Appeals should be addressed to the cognizant appellate authority. The addresses of the SECNAV's designees are:

(1) Judge Advocate General, Navy Department, 200 Stovall Street, Alexandria, VA 22332-2400.

(2) General Counsel, Navy Department, Washington, DC 20360-5110.

(e) *Time limits for filing FOIA appeals.* (1) The requester should file the appeal so it reaches the appellate authority not later than 60 calendar days from the date of the initial denial letter. At the end of 60 calendar days, the case may be considered closed; however, the requester may file litigation for denial of the appeal. If the requester was provided several incremental determinations for a single request, the time limit for filing the appeal begins when the requester receives the last response. Records which are denied shall be retained for a period of six years to meet the statute of limitations of claims requirement.

(2) Final determinations on appeals shall normally be made within 20 working days after receipt.

(f) *Delay in responding to a FOIA appeal.* If additional time is needed due to unusual circumstances, the final decision may be delayed for the number of working days (not to exceed 10), that were not utilized as additional time for responding to the initial request. If a determination cannot be made and the requester is notified within 20 working days, the appellate authority shall acknowledge to the requester in writing the date of receipt of the appeal, circumstances for the delay, and anticipated date for substantive response. Requesters may be advised that if the delay exceeds the statutory extension or is for reasons other than "unusual circumstances," they may consider their administrative remedies exhausted. Further, requesters should be advised that they may wait for a substantive response without prejudicing their right to judicial remedy. The appellate authority shall continue to process the case expeditiously whether or not the requester seeks a court order for release of the record(s). A copy of any response provided subsequent to filing of a complaint shall be forwarded to the Department of Justice.

(g) *Action upon receipt.* Upon receipt of a FOIA appeal, NJAG or OGC shall inform the cognizant IDA of receipt of the appeal. The appellate authority will seek documentation from the IDA from which to make a determination. Normally, the IDA will be requested to forward a copy of the initial request, a copy of the response, a copy of excised

and unexcised documents, and supporting rationale for continued withholding (if applicable) to the appellate authority within 10 working days.

(h) *Consultation/coordination.* (1) The Assistant for Naval Investigative Matters and Security (OP-09N) may be consulted to resolve inconsistencies or disputes involving classified records.

(2) Direct liaison with appropriate officials within the Department of the Navy and other interested federal agencies is authorized at the discretion of the appellate authority, who also coordinates with appropriate Department of Defense officials and Justice as prescribed by directives of the Secretary of Defense (SECDEF).

(3) SECNAV or appropriate Civilian Executive Assistants shall be consulted and kept advised of cases with unusual implications. CHINFO shall be consulted and kept advised on cases having public affairs implications.

(i) *Response to the requester.* (1) When an appellate authority makes a determination to release all or a portion of records withheld by an IDA, a copy of the records released should be promptly forwarded to the requester after compliance with any procedural requirements, such as payment of fees.

(2) Final denial to provide a requested record or to approve a request to waive or reduce fees must be made in writing by the appellate authority. The response shall include the following:

(i) An explanation of the basis for the denial including the applicable statutory exemption(s) invoked.

(ii) If the final denial is based in whole or in part on a security classification, the explanation shall include a determination that the record meets the cited criteria and rationale of the governing Executive Order, is based on a declassification review, and the review confirmed the continuing validity of the security classification.

(iii) The response shall advise the requester that the material denied does not contain reasonably segregable portions.

(iv) The response shall advise the requester of the right to judicial review.

(v) The final denial shall include the name and title of the official responsible for the denial.

(vi) An information copy, less attachments, should be provided to CNO (OP-09B30).

(j) *Judicial actions.* A requester may seek an order from a U.S. District Court to compel release of a record after exhaustion of administrative remedies, i.e., the IDA or appellate authority denied release or when a naval activity failed to respond within the prescribed time limits.

(1) Burden of proof. The naval activity has the burden of proof to justify its refusal to provide a record. The court evaluates the case de novo (anew) and may examine any requested record in camera (in private) to determine whether the denial was justified.

(2) Actions by the court.

(i) When a naval activity fails to make a determination within the statutory time limits but can demonstrate due diligence in exceptional circumstances, the court may retain jurisdiction and allow the naval activity additional time to complete its review of the records.

(ii) If the court determines that the requester's complaint is substantially correct, it may require the United States to pay reasonable attorney fees and other litigation costs.

(iii) When the court orders the release of denied records, it may also issue a written finding that the circumstances surrounding the withholding raise questions whether civilian personnel acted arbitrarily and capriciously. In these cases, the special counsel of the Merit Systems Protection Board will conduct an investigation to determine whether or not disciplinary action is warranted. The naval activity is obligated to take the action recommended by the special counsel.

(iv) When a naval activity fails to comply with the court order to produce records that have been withheld improperly, the court may punish the responsible official for contempt.

(3) Non-United States Government source information. A requester may bring suit in a U.S. District Court to compel the release of records obtained from a non-government source or records based on information obtained from a non-government source. The source shall be notified promptly of the court action. If the source advises that it is seeking court action to prevent release, the naval activity shall defer answering or otherwise pleading to the complaint as long as permitted by the Court or until a decision is rendered in the court action initiated by the source, whichever is sooner.

§ 701.11 Publication, indexing, and public inspection of certain classes of records.

Secretary of the Navy Instruction 5720.45[2], "Indexing, Public Inspection, and Federal Register Publication of Department of the Navy Directives and other Documents Affecting the Public," assigns the heads of Department of the Navy components, Commanders of the Naval Systems Commands, and the Military Sealift Command responsibilities for executing the following additional requirements on records under their respective cognizance:

(a) Publication of certain classes of Department of the Navy organizational, regulatory, policy, procedural, interpretative, and substantive records on a current basis in the **Federal Register**, for the guidance of the public.

(b) Maintenance of current indexes of various classes of records which are precedential for decisions affecting members of the public, and publication of such indexes at least quarterly or making them available to the public by other authorized means.

(c) Making the above records and indexes regularly available for public inspection and copying at naval locations.

[2] Copies may be obtained if needed, from the Commanding Officer, U.S. Naval Publications and Forms Center, 5801 Tabor Avenue, Philadelphia, PA 19120-5099.

Subpart B—FOIA Exemption Guidelines

§ 701.21 General.

(a) The FOIA is a disclosure statute whose goal is an informed citizenry. Because of this records are considered to be releasable unless they contain information that qualifies for withholding under one or more of the nine FOIA exemptions. The exemptions are identified as 5 U.S.C. 552 number (b)(1) through (b)(9).

(b) Even though a document may contain information which qualifies for withholding under one or more FOIA exemptions, FOIA requires that all "reasonably segregable" information be provided to the requester, unless the segregated information would have no meaning. In other words, redaction is not required when it would reduce the balance of the text to "unintelligible gibberish."

(c) The decision to withhold information in whole or in part based on one or more of the FOIA exemptions requires the signature of an Initial Denial Authority (IDA). See paragraph (e) of § 701.5 for a listing of IDAs.

(d) The following types of records may be withheld in whole or in part from public disclosure under FOIA, unless otherwise prescribed by law. A discretionary release to one requester may preclude the withholding of the same records under a FOIA exemption if the record is subsequently requested by someone else. In applying exemptions,

the identity of the requester and the purpose for which the record is sought are irrelevant with the exception that an exemption may not be invoked where the particular interest to be protected is the requester's interest.

§ 701.22 Exemption (b)(1).

Those properly and currently classified in the interest of national defense or foreign policy, as specifically authorized under criteria established by Executive Order (i.e., Executive Order 12356) and implemented by regulations. Although material is not classified at the time of the FOIA request, a classification review may be undertaken to determine whether the information should be classified. The procedures in OPNAVINST 5510.1H, "Department of the Navy Information and Personnel Security Program Regulation" apply. In addition, this exemption shall be invoked when the following situations are apparent:

(a) The fact of the existence or nonexistence of a record would itself reveal classified information. In that situation, naval activities shall neither confirm nor deny the existence or nonexistence of the record being requested. A "refusal to neither confirm nor deny" response must be used consistently, not only when a record exists, but also when a record does not exist. Otherwise, the pattern of using a "no record" response when a record does not exist, and a "refusal to neither confirm nor deny" when a record does exist will itself disclose national security information. That kind of response is referred to as a "Glomar" denial.

(b) Information that concerns one or more of the classification categories established by Executive order and OPNAVINST 5510.1 series, "Department of the Navy Information and Personnel Security Program Regulation," shall be classified if its unauthorized disclosure, either by itself or in the context of other information, reasonably could be expected to cause damage to the national security.

§ 701.23 Procedures for processing classified documents.

(a) The threshold for claiming exemption (b)(1) is that the document is properly and currently classified. Because of that, naval activities should normally refer requests for classified documents to the activity that originally classified the information. If the referring activity has an interest in the matter, they should also provide the receiving activity with a release determination. The receiving activity will then conduct a declassification review and apprise the requester of their determination, i.e., documents are properly and currently classified and therefore must be denied; portions of the documents are releasable; etc. Only an official authorized under § 701.5 to deny requests and who has cognizance over the classified matters in the records, may deny records. Such denial must be based on an approved security classification guide issued under OPNAVINST 5510.1 series or OPNAVINST 5513 series; resource document originated by another naval activity or government agency; an original classification determination with written justification for classification, and the justification remains valid; or, not readily identifiable, but classification is believed warranted because of classification criteria in OPNAVINST 5510.1 series, "Department of the Navy Information and Personnel Security Program."

(b) Material that is not classified at the time of the FOIA request may undergo a classification review to determine whether the information should be classified (ensure strict compliance with the provisions of OPNAVINST 5510.1 series regarding classification of information after receipt of a FOIA request).

(c) Executive Order 12356 provides that "information shall be classified as long as required by national security considerations, and time frame no longer triggers automatic declassification."

(d) If the original classifier of a record receives a request for the record and upon review determines that there is no basis for continued classification, either in whole or part, the record or portions of it should be declassified. The document also undergoes another review to determine whether any other FOIA exemptions apply to the declassified information.

(e) In some instances, the compilation of unclassified information may result in the classification of the record as a whole. This is called the "mosaic" approach—the concept that apparently harmless pieces of information, when assembled together could reveal a damaging picture.

§ 701.24 Exemption (b)(2).

Those related solely to the internal personnel rules and practices of an agency. This exemption has two profiles, high (b)(2) and low (b)(2).

(a) Records qualifying under high (b)(2) are those containing or constituting statutes, rules, orders, manuals, directives, and instructions the release of which would allow circumvention of the records thereby substantially hindering the effective performance of a significant function of the Department of the Navy. Examples include:

(1) Those operating rules, guidelines, and manuals for Department of the Navy investigators, inspectors, auditors, or examiners that must remain privileged in order for the naval activity to fulfill a legal requirement.

(2) Personnel and other administrative matters, such as examination questions and answers used in training courses or in the determination of the qualifications of candidates for employment, entrance on duty, advancement, or promotion.

(3) Computer software, the release of which would allow circumvention of a statute or Department of the Navy rules, regulations, orders, manuals, directives, or instructions. In this situation, the use of the software must be closely examined to ensure the possibility of circumvention exists.

(4) Security classification guides.

(b) Records qualifying under the low (b)(2) profile are those that are trivial and housekeeping in nature for which there is no legitimate public interest or benefit to be gained by release, and it would constitute an administrative burden to process the request in order to disclose the records. Examples include, rules of personnel's use of parking facilities or regulation of lunch hours, statements of policy as to sick leave, and trivial administrative data such as file numbers, mail routing stamps, initials, data processing notations, brief references to previous communication, and other like administrative markings.

§ 701.25 Exemption (b)(3).

Those concerning matters that a statute specifically exempts from disclosure by terms that permit no discretion on the issue, or under criteria established by that statute for withholding or referring to particular types of matters to be withheld. Authorization or requirement may be found in the statute itself or in Executive orders or regulations authorized by, or in implementation of a statute. Examples include:

(a) National Security Agency Information Exemption, Pub. L. 86-36, Section 6.

(b) Patent Secrecy, 35 U.S.C. 181-188—any records containing information relating to inventions that are the subject of patent applications on which Patent Secrecy Orders have been issued.

(c) Restricted Data and Formerly Restricted Data, 42 U.S.C. 2162.

(d) Communication Intelligence, 18 U.S.C. 798.

(e) Authority to Withhold From Public Disclosure Certain Technical Data, 10 U.S.C. 130.

(f) Confidentiality of Medical Quality Records: Qualified immunity Participants, 10 U.S.C. 1102.

(g) Physical Protection of Special Nuclear Material: Limitation on Dissemination of Unclassified Information, 10 U.S.C. 128. This statute prohibits the unauthorized dissemination of unclassified information pertaining to security measures, including security plans, procedures, and equipment for the physical protection of special nuclear material.

(h) Protection of Intelligence Sources and Methods, 50 U.S.C. 403(d)(3).

(i) 42 U.S.C. 4582—alcohol abuse prevention/rehabilitation. Records of the identity, diagnosis, prognosis, or treatment of any patient maintained in connection with the performance of any drug abuse prevention function conducted, regulated, or directly assisted by any department or agency of the U.S., unless expressly authorized.

(j) Examples of statutes which DO NOT qualify under exemption (b)(3) include: 5 U.S.C. 552(a), Privacy Act; 17 U.S.C. 101 et. seq, Copyright Act; 18 U.S.C. 793, Gathering, Transmitting or Losing Defense Information; 18 U.S.C. 794, Gathering or Delivering Defense Information to Aid Foreign Governments; 18 U.S.C. 1905, Trade Secrets Act; and, 28 U.S.C. 1498, Patent and Copyright Cases.

§ 701.26 Exemption (b)(4).

Those containing trade secrets or commercial or financial information that a naval activity receives from a person or organization outside the Government with the understanding that the information or record will be retained on a privileged or confidential basis. Records within the exemption must contain trade secrets, or commercial or financial records, the disclosure of which is likely to cause substantial harm to the competitive position of the source providing the information, impair the government's ability to obtain necessary information in the future, or impair some other legitimate government interest. Examples include:

(a) Commercial or financial information received in confidence in connection with loans, bids, contracts, or proposals, as well as other information received in confidence or privileged such as trade secrets, inventions and discoveries, or other proprietary data.

(b) Statistical data and commercial or financial information concerning contract performance, income, profits, losses, and expenditures, if offered and received in confidence from a contractor or potential contractor.

(c) Personal statements given in the course of inspections, investigations, or audits, when such statements are received in confidence from the individual and retained in confidence because they reveal trade secrets or commercial or financial information normally considered confidential or privileged.

(d) Financial data provided in confidence by private employers in connection with local wage surveys used to fix and adjust pay schedules applicable to the prevailing wage rate for employees within the Department of the Navy.

(e) Scientific and manufacturing processes or developments concerning technical or scientific data or other information submitted with an application for a research grant, or with a report while research is in progress.

(f) Technical or scientific data developed by a contractor or subcontractor exclusively at private expense, or developed in part with federal funds and in part at private expense, where the contractor or subcontractor retains a legitimate proprietary interest in the data under 10 U.S.C. 2320-2321 and DOD Federal Acquisition Regulation Supplement (DFARS), subpart 27.4. Technical data developed exclusively with federal funds may be withheld under exemption (b)(3) if it meets the criteria of 10 U.S.C. 130.

(g) Computer software which is copyrighted under the Copyright Act of 1976 (17 U.S.C. 106), the disclosure of which would have an adverse impact on the potential market value of a copyrighted work.

Note: The status of unit prices in awarded in government contracts, once a controversial issue, has become more settled with recent court decisions. The courts have held that disclosure of unit prices would not directly reveal confidential proprietary information, such as a company's overhead, profit rates, or multiplier, and that the possibility of competitive harm was thus too speculative.

§ 701.27 Exemption (b)(5).

Those records containing internal advice, recommendations, and subjective evaluations, as contrasted with factual matters, that are reflected in records pertaining to the decision-making process of an agency, whether between agencies or between Department of Defense and Department of the Navy components, except as provided in § 701.27 number (b) through (e). Also exempted are records pertaining to the attorney-client privilege and the attorney work-product privilege.

(a) Examples include:

(1) Nonfactual portions of staff papers, to include after-action reports and situation reports containing staff evaluations, advice, opinions, or suggestions.

(2) Advice, suggestions, or evaluations prepared on behalf of Department of the Navy individual consultants or by boards, committees, councils, groups, panels, conferences, commissions, task forces, or other similar groups formed for the purpose of obtaining advice and recommendations.

(3) Nonfactual portions of evaluations by Department of the Navy personnel of contractors and their products.

(4) Information of a speculative, tentative, or evaluative nature on proposed plans to procure, lease, or otherwise acquire and dispose of materials, real estate, facilities, or functions, when such information would provide undue or unfair competitive advantage to private personal interests or would impede legitimate government functions.

(5) Trade secret or other confidential research development, or commercial information owned by the Government, where premature release is likely to affect the Government's negotiating position or other commercial interests.

(6) Records that are exchanged among agency personnel and between Department of the Navy, Department of Defense, or other agencies in preparation for anticipated administrative proceeding by an agency or litigation before any federal, state, or military court, as well as records that qualify for the attorney-client privilege.

(7) Portions of official reports of inspection, reports of the Inspector Generals, audits, investigations, or surveys pertaining to safety, security, of the internal management, administration, or operation of one or more naval activities, when these records have traditionally been treated by courts as privileged against disclosure in litigation.

(8) Computer software meeting the standards of § 701.3(b)(3) which is deliberative in nature, the disclosure of which would inhibit or chill the decision making process. In that situation, the use of software must be closely examined to ensure its deliberative nature.

(9) Planning, programming, and budgetary information which is involved in the defense planning and resource allocation process.

(b) If any such intra- or interagency record or reasonably segregable portion of such record would be made available routinely through the "discovery process" (the legal process by which litigants obtain information from each other relevant to the issues in a trial or hearing) in the course of litigation with Department of the Navy, such record, should not be withheld even though discovery has not been sought in actual litigation. If, the information could only be made available through the discovery process by special order of the court based on the needs of a litigant balanced against the interests of the Department of the Navy in maintaining its confidentiality, the record or document need not be made available under this instruction. Consult with legal counsel to determine whether exemption (b)(5) material would be routinely made available through the discovery process.

(c) Intra- or interagency memoranda or letters that are factual, or those reasonably segregable portions that are factual, are routinely available through "discovery" and shall be made available to a requester, unless the factual material is otherwise exempt from release, inextricably intertwined with the exempt information, so fragmented as to be uninformative, or so redundant of information already available to the requester as to provide no new substantive information.

(d) A direction or order from a superior to a subordinate contained in internal communication cannot be withheld from a requester if it constitutes policy guidance or a decision, as distinguished from a discussion of preliminary matters or a request for information or advice that would compromise the decision-making process.

(e) An internal communication on a decision subsequently made a matter of public record must be made available to a requester when the rationale for the decision is expressly adopted or incorporated by reference in the record containing the decision.

§ 701.28 Exemption (b)(6).

Information in personnel and medical files, and similar files, that if disclosed to the requester would result in a clearly unwarranted invasion of personal privacy. Release of information about an individual contained in a Privacy Act (PA) system of records that would constitute a clearly unwarranted invasion of privacy is prohibited, and could subject the releaser to civil and criminal penalties.

(a) Examples of files other than personnel and medical files containing similar personal information include:

(1) Those compiled to evaluate or adjudicate the suitability of candidates for civilian employment or membership in the Armed Forces, and the eligibility of individuals (civilian, military, or contractor employees) for security clearances, or for access to particularly sensitive classified information.

(2) Files containing reports, records, and other material pertaining to personnel matters in which administrative action, including disciplinary action, may be taken.

(b) Home addresses are normally not releasable without the consent of the individuals concerned. In addition, lists of Department of the Navy military and civilian personnel's names and duty addresses who are assigned to units that are sensitive, routinely deployable, or stationed in foreign territories can constitute a clearly unwarranted invasion of personal privacy.

(1) Privacy interest. A privacy interest may exist in personal information even though the information has been disclosed at some place and time. If personal information is not freely available from sources other than the Federal Government, a privacy interest exists in its nondisclosure. The fact that the Federal Government expended funds to prepare, index and maintain records on personal information, and the fact that a requester invokes FOIA to obtain these records indicates the information is not freely available.

(2) Published telephone directories, organizational charts, rosters and similar materials for personnel assigned to units that are sensitive, routinely deployable, or stationed in foreign territories are withholdable under exemption (b)(6).

(c) This exemption is relevant to a request for information that is intimate to an individual or that possibly could have adverse effects upon that individual or his or her family if disclosed. Subpart F of this Part 701 lists several examples of non-derogatory information about the official character of a naval member or employee that can routinely be disclosed to a member of the public without constituting a clearly unwarranted invasion of personal privacy of the individual concerned.

(d) Individuals' personnel, medical, or similar files may be withheld from them or their designated legal representative only to the extent consistent with PA.

(e) When determining whether a release is "clearly unwarranted," the public interest in release must be balanced against the sensitivity of the privacy interest threatened. For example, lists of names and duty addresses of Department of the Navy personnel (civilian and military) assigned to units that are sensitive, routinely deployable, or stationed in foreign territories must be withheld because release could aid in the targeting of Department of the Navy employees and their families by terrorists. See paragraph (p) of § 701.8 regarding requests for mailing lists.

(f) When withholding information solely to protect the personal privacy of the subject of the record, information should not be withheld from that individual or from his or her designated representative. The personal privacy of others discussed in that record may constitute a basis for deleting reasonably segregable portions of the record even when providing it to the subject of the record. This exemption shall not be exercised in an attempt to protect the privacy of a deceased person but may be used to protect the privacy of the deceased person's family.

(g) Individual's personnel, medical, or similar file may be withheld from them or their designated legal representative only as consistent with SECNAVINST 5211.5C, "Personal Privacy and Rights of Individuals Regarding Records Pertaining to Themselves."

(h) A clearly unwarranted invasion of the privacy of the persons identified in a personnel, medical, or similar record may constitute a basis for deleting those reasonably segregable portions of that record, even when providing it to the subject of the record. When withholding personal information from the subject of the record, legal counsel should first be consulted.

§ 701.29 Exemption (b)(7).

Records or information compiled for law enforcement purposes, (i.e., civil, criminal, or military law, including the implementation of Executive orders or regulations issued pursuant to law). This exemption may be invoked to prevent disclosure of documents not originally created for, but later gathered for law enforcement purposes.

(a) This exemption applies, however, only to the extent that production of such law enforcement records or information:

(1) Could reasonably be expected to interfere with enforcement proceedings (5 U.S.C. 552(b)(7)(A));

(2) Would deprive a person of the right to a fair trial or an impartial adjudication (5 U.S.C. 552(b)(7)(B));

(3) Could reasonably be expected to constitute an unwarranted invasion of personal privacy of a living person, including surviving family members of an individual identified in such a record (5 U.S.C. 552(b)(7)(C));

(i) This exemption also applies when the fact of the existence or nonexistence of a responsive record would itself reveal personally private information, and the public interest in disclosure is not sufficient to outweigh the privacy interest. In this situation, naval activities shall neither confirm nor deny the existence or non-existence of the record being requested.

(ii) A refusal to "neither confirm nor deny" response must be used consistently, not only when a record exists, but also when a record does not exist. Otherwise, the pattern of using a "no records" response when a record does not exist and a "refusal to neither confirm nor deny" when a record does exist will itself disclose personally private information.

(iii) Refusal to "neither confirm nor deny" should not be used when the person whose personal privacy is in jeopardy has provided the requester with a waiver of his or her privacy rights; or, the person whose personal privacy is in jeopardy is deceased, and the agency is aware of that fact.

(4) could reasonably be expected to disclose the identity of a confidential source, including a source within the DON, a state, local, or foreign agency or authority, or any private institution which furnishes information on a confidential basis; could disclose information furnished from a confidential source and obtained by a criminal law enforcement authority in a criminal investigation or by an agency conducting a lawful national security intelligence investigation (5 U.S.C. 552 (b)(7)(D));

(5) Would disclose techniques and procedures for law enforcement investigations or prosecutions, or would disclose guidelines for law enforcement investigations or prosecutions, if such disclosure could reasonably be expected to risk circumvention of the law (5 U.S.C. 552(b)(7)(E)); or,

(6) Could reasonably be expected to endanger the life or physical safety of any individual (5 U.S.C. 552(b)(7)(F)).

(b) Examples include:

(1) Statements of witnesses and other material developed during the course of the investigation and all materials prepared in connection with related government litigation or adjudicative proceedings.

(2) The identity of firms or individuals investigated for alleged irregularities involving contracting with Department of Defense or Department of the Navy when no indictment has been obtained nor any civil action filed against them by the United States.

(3) Information obtained in confidence, expressed or implied, in the course of a criminal investigation by a criminal law enforcement agency or office within Department of Defense, or a lawful national security intelligence investigation conducted by an authorized agency or office within Department of Defense. National security intelligence investigations include background security investigations conducted for the purpose of obtaining affirmative or counterintelligence information.

(c) The right of individual litigants to investigate records currently available by law.

(d) When the subject of an investigative record is the requester of the record, it may be withheld only as authorized by SECNAVINST 5211.5C, "Personal Privacy and Rights of Individuals Regarding Records Pertaining to Themselves."

(e) Exclusions. Excluded from this exemption are the following two situations:

(1) Whenever a request is made which involves access to records or information complied for law enforcement purposes, and the investigation or proceeding involves a possible violation of criminal law where there is reason to believe that the subject of the investigation or proceeding is unaware of its pendency, and the disclosure of the existence of the records could reasonably be expected to interfere with enforcement proceedings, naval activities may, during only such times as those circumstances continue, treat the records or information as not subject to exemption 7. In such situation, the response to the requester will state no records were found.

(2) Whenever informant records maintained by a criminal law enforcement organization within DON under the informant's name or personal identifier, the naval activity may treat the records as not subject to exemption 7, unless the informant's status as an informant has been officially confirmed. If it is determined that the records are not subject to exemption 7, the response to the requester will state no records were found.

§ 701.30 Exemption (b)(8).

Exempts those records contained in or related to examination, operation, or condition reports prepared by, on behalf of, or for the use of an agency responsible for the regulation or supervision of financial institutions.

§ 701.31 Exemption (b)(9).

Exempts those records containing geological and geophysical information and data, including maps, concerning wells.

Subpart C—Addresses for Department of the Navy records and locations for public inspection

§ 701.31 Addresses for requests for Department of the Navy records.

The following addresses delineate the location of commonly requested information. Members of the public are encouraged to write directly to the official having cognizance over the record(s), as it will expedite processing. When the official having custody of the record is not known, the request should be addressed to the originating official or the official having primary responsibility for the subject matter involved. The following are the most commonly requested types of records:

(a) *Audit reports.* Send requests for internal audit matters to the Auditor General of the Navy, P.O. Box 1206, Falls Church, VA 22041-0206.

(b) *Chaplain Corps.* Send requests for religious affairs matters to the Chief of Chaplains, Navy Department, Washington, DC 20370-2000.

(c) *Civilian personnel records.* (1) Send requests for personnel records of current civilian employees, or those separated from Federal employment less than 30 days, to the employing installation marked for the attention of the civilian personnel officer.

(2) Send requests for individuals formerly employed by the Department of the Navy, or separated from Federal employment for more than 30 days, to the Director, National Personnel Records Center, (Civilian Personnel Records), 111 Winnebago Street, St. Louis, MO 63118.

(d) *Contractual/procurement records and related matters.* (1) Send requests for copies of Navy procurement directives and Defense Federal Acquisition Regulations (DFARs) to the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

(2) Send requests for copies of current contracts to the contracting officer or head of the procurement activity when known. If unknown, submit requests for Navy contracts to the Chief of Naval Operations (OP-09B30), Pentagon, Washington, DC 20350-2000 and Marine Corps contracts to the Deputy Chief of Staff for Installations and Logistics, U.S. Marine Corps, Washington, DC 20380-0001.

(e) *Courts-martial records.* (1) Send requests for records of trial by general courts-martial, or special courts-martial which resulted in a bad conduct

discharge, or involving commissioned officers to the Judge Advocate General, Code 20, 200 Stovall Street, Alexandria, VA 22332-2400.

(2) Send requests for records of trial by summary courts-martial or special courts-martial not involving a bad conduct discharge to the officer having supervisory authority in the review process.

(f) *Naval Inspector General Reports.* Send requests for Navy hotline complaints and all other investigations and inspections conducted by the NAVINSGEN to the Navy Inspector General, Navy Department, Washington, DC 20370-2001. Send requests for local command Inspector General reports to the local IG office.

(g) *Investigative records.* (1) Send requests for NIS investigatory records and related matters to the Commander, Naval Investigative Service Command, Washington, DC 20388-5000.

(2) Send requests for JAG Manual investigative reports to the Judge Advocate General (Code 33), Navy Department, 200 Stovall Street, Alexandria, VA 22332-2400.

(3) Send requests for mishap investigative reports to the Commander, Naval Safety Center (Code 50), Naval Air Station, Norfolk, VA 23511-5796.

(h) *Legal matters.* (1) General Counsel legal matters. Those relating to the acquisition, custody, management, transportation, taxation, and disposition of real and personal property, and the procurement of services, including the fiscal, budgetary, and accounting aspects thereof, excepting, however, tort claims and admiralty claims arising independently of contract, and matters relating to the naval petroleum reserves; operations of the Military Sealift Command, excepting tort and admiralty claims arising independently of contract; the Office of the Comptroller of the Navy; procurement matters in the field of patents, inventions, trademarks, copyrights, royalty payments, and similar matters, including those in the Defense Federal Acquisition Regulations (DFARs), and Navy procurement directives; and, industrial security claims and litigation should be directed to the Office of Counsel of the concerned activity. If unknown, submit to the General Counsel, Navy Department, Washington, DC 20360.

(2) Judge Advocate General legal matters. In addition to military law, all matters except those outside the jurisdiction of the General Counsel should be directed to the Judge Advocate General, 200 Stovall Street, Alexandria, VA 22332-2400.

(i) *Medical records.* (1) Send requests for inpatient medical treatment records of active duty Navy and Marine Corps personnel and their dependents to the medical treatment facility where the patient is or was treated. The records are held for two years and then retired to the National Personnel Records Center, 9700 Page Avenue, St. Louis, MO 63132-5100.

(2) Send requests for outpatient medical treatment records of active duty Navy and Marine Corps personnel and their dependents to the military treatment facility attached to the command at which they are assigned.

(3) Send requests for outpatient medical records of Navy personnel separated (discharged, retired, or deceased) for less than 4 months to the Commanding Officer, Naval Reserve Personnel Center, New Orleans, LA 70149-7800. After four months, send requests to Director, National Personnel Records Center, (Military Personnel Records), 9700 Page Avenue, St. Louis, MO 63132-5100. Send requests for dependents' outpatient records to the last medical facility where treatment was provided if within 2 years of sponsor's release/separation from the service. After the 2 years, send requests to Director, National Personnel Records Center, (Military Personnel Records), 9700 Page Avenue, St. Louis, MO 63132-5100.

(4) Send requests for outpatient medical records of Marine Corps personnel separated (discharged, retired, or deceased) for less than four months to Director, Marine Corps Reserve Support Center, 10950 El Monte Street, Overland Park, KS 66211-1408. After four months, send requests to Director, National Personnel Records Center, (Military Personnel Records), 9700 Page Avenue, St. Louis, MO 63132-5100. Requests for dependents' outpatient records should be addressed to the last medical facility where treatment was provided if within 2 years of active duty member's release/separation from the service. After two years, send requests to Director, National Personnel Records Center, (Military Records Center), 9700 Page Avenue, St. Louis, MO 63132-5100.

(5) When the location of a military member or dependent's medical record is not known, send requests to Chief, Bureau of Medicine and Surgery, Navy Department, Washington, DC 20372-5120.

(6) Send requests for medical records of drilling reservists to the reserve centers where they are assigned.

(7) Send requests for medical records of inactive or retired reservists to Commanding Officer, Naval Reserve Personnel Center, New Orleans, LA 70149-7800.

(8) *Civilian employee medical records.* Send requests to the medical facility where the person is/was treated. After 2 years, send requests to Director, National Personnel Records Center, (Civilian Personnel Records), 111 Winnebago Street, St. Louis, MO 63118.

(j) *Military personnel records.* (1) Send requests for records of active duty Navy personnel, or those separated (discharged, retired or deceased for up to 1 year) to Chief, Bureau of Naval Personnel, Navy Department, Washington, DC 20378-5000 and for Marine Corps personnel to Commandant of the Marine Corps, (Code MM), Navy Department, Washington, DC 20380-0001.

(2) Send requests for records of Navy and Marine Corps personnel separated (discharged, retired or deceased) for more than 1 year and inactive reservists to Director, National Personnel Records Center, (Military Personnel Records), 9700 Page Avenue, St. Louis, MO 63132-5100.

(3) Send requests for former officer personnel separated prior to 1902 and former enlisted personnel separated prior to 1885 to Chief, Military Reference Branch, Military Archives Division, National Archives, Washington, DC 20408.

(4) Send requests for records of drilling reservists to the member's servicing personnel support unit.

(5) Send requests for records of inactive duty reservists who still have an obligation to the Navy to the Commanding Officer, Naval Reserve Personnel Center, New Orleans, LA 70149-7800.

(6) Send requests for records of separated reservists who have not retired to the Director, National Personnel Records Center, (Military Personnel Records), 9700 Page Avenue, St. Louis, MO 63132-5100.

(7) Send requests for records of retired reservists to the Commanding Officer, Naval Reserve Personnel Center, New Orleans, LA 70149-7800.

(k) *Publications.* (1) Send requests for unclassified instructions, other than Secretary of the Navy Instructions, issued under the Department of the Navy's directives issuance system and subject index thereof (NAVPUBINST 5215.1B) to the Commanding Officer, Naval Publications and Forms Center, 5801 Tabor Avenue, Philadelphia, PA 19120-5099.

(2) Send requests for all SECNAVINSTs and OPNAVINSTs marked FOUO or classified to the CNO (OP-09B30), Pentagon, Washington, DC 20350-2000.

(3) Send requests for Marine Corps directives, publications, and manuals to Commandant of the Marine Corps, (Code AR), Navy Department, Washington, DC 20380-0001.

(4) Send requests for military specifications, standards, and handbooks to the Commanding Officer, Naval Publications and Forms Center, 5801 Tabor Avenue, Philadelphia, PA 19120-5099.

(l) *Research records.* Send requests for records regarding basic research and grants to the activity having custody of the record. If unknown, send to the Chief of Naval Research, 800 North Quincy Street, Arlington, VA 22217-5000.

(m) *Systems commands.* (1) *Aeronautical weapon systems.* Send requests for information on aeronautical weapon systems, associated subsystems and related systems and equipment to the Commander, Naval Air Systems Command, Naval Air Systems Command Headquarters, Washington, DC 20361-0001.

(2) *Facilities.* Send requests for information on facilities and land management (design, construction, and maintenance; utilities; housing; and real estate matters) to the Commander, Naval Facilities Engineering Command, 200 Stovall Street, Alexandria, VA 22332-2300.

(3) *Ships.* Send requests for information on ships and ordnance materials to the Commander, Naval Sea Systems Command, Naval Sea Systems Command Headquarters, Washington, DC 20362-5101.

(4) *Space and Naval Warfare.* Send requests for information on development technologies regarding battle force architecture and engineering, space communications, navigation, undersea and ocean surveillance, oceanographic matters, anti-submarine warfare, information transfer systems, and information management systems to the Commander, Space and Naval Warfare Systems Command, Washington, DC 20363-5100.

(5) *Supply.* Send requests for information on naval supply matters to the Commander, Naval Supply Systems Command, Naval Supply Systems Command Headquarters, Washington, DC 20376-5000 and for Marine Corps supply matters to the Commandant of the Marine Corps, (Code L), HQ USMC, Washington, DC 20380-0001.

(n) *Ships decklogs.* Send requests for ships decklogs originating after 30 June 1945 to the Director, Naval Historical Center, Ships' Histories Section, Washington Navy Yard, Washington, DC 20374. Those originated prior to 1945 are held by the Chief, Military Reference Branch, Military Archives Division, National Archives, Washington, DC 20408.

(o) *Supply catalogs.* Send requests for Navy and Federal supply catalogs, master cross-reference indexes, and related cataloging publications (cataloging handbooks such as H2-1 and H2-3 and Federal manuals for supply cataloging, such as M1-1, -2 and -3) to Superintendent of Documents, United States Government Printing Office, Washington, DC 20402-9325.

(p) *Technical reports.* Send requests for unclassified technical reports or publications to the Director, National Technical Information Service, 5285 Port Royal Road, Springfield, VA 20402.

(q) *Unknown.* If requesters are unable to determine the official having cognizance over the requested records, they should send their request for naval matters to the Chief of Naval Operations, (Code 09B30), Pentagon, Washington, DC 20350-2000 and Marine Corps matters to Commandant of the Marine Corps, HQMC (Code MI-3), Navy Department, Washington, DC 20380-0001.

§ 701.32 Locations at which Department of the Navy records are available for public inspection.

(a) *Navy Department Library.* The Navy Department Library is located at the Washington Navy Yard, Building 44, 9th and M Streets, SE, Washington, DC 20374-0571.

(1) *Hours of Operation.* 9 a.m. to 4 p.m., Monday through Friday, except holidays.

(2) *Type of Materials Held.* The library has 130,000 volumes of information of interest to the Navy, such as naval and general history, international law and diplomacy, naval architecture and shipbuilding, naval customs and traditions, naval shore stations, yards and bases, uniforms, insignia, awards and flags, geography, travel and guide books, aviation, Navy music, etc. Also contained are approximately 5,000 rare book collections. Additionally, the library has an index by subject matter of materials held, i.e., NAVPUBINST 5215.1B, Consolidated Subject Index, a quarterly publication which lists instructions originated by Washington Headquarters organizations and Marine Corps directives system checklist of directives distributed outside Headquarters, U.S. Marine Corps. The library is equipped with desks and study carrels for library users and has specialized devices to facilitate research, such as microfilm reader/printers, copy machines, and outlets for tape recorders.

(b) *Defense Reading Room.* The Defense Reading Room is located in Room 2E165 of the Pentagon, Washington, DC 20310-1400. Due to building security, upon arrival at the Pentagon, call 695-3973 to arrange for an escort to the Reading Room.

(1) *Hours of Operation.* 8 a.m. to 4 p.m., Monday through Friday, except holidays.

(2) *Type of Materials Held.* Microfiche copies of indexes and decisional documents regarding Navy Discharge Review Board and Board for Correction of Naval Records proceedings.

(c) *Law Library of the Judge Advocate General.* The law library is located at the Hoffman Building 2, Room 9S47, 200 Stovall Street, Alexandria, VA 22332-2400.

(1) *Hours of Operation.* 9 a.m. to 4 p.m., Monday through Friday, except holidays.

(2) *Type of Materials Held.* The library has published and unpublished decisions of the Navy-Marine Corps Court of Military Review, Navy and Marine Corps directives, miscellaneous superseded manuals, and courts-martial orders and the Navy Department Bulletin.

Subpart D—Fee Guidelines

§ 701.40 FOIA Fees.

(a) *Background.* The FOIA Reform Act of 1986 brought about significant changes on how FOIA fees are assessed. Subpart D of this part highlights in detail the changes made and conforms with the Office of Management and Budget (OMB) Uniform Fee Schedule and Guidelines which were issued as a result of the Reform Act. OMB guidelines for fees reflect direct costs for search, review (in the case of commercial requesters), and duplication of documents, collection of which are permitted by FOIA.

(b) *DD Forms 2086/2086-1.* Naval activities are encouraged to utilize DD Forms 2086/2086-1 to track costs for each FOIA request processed, unless a standard processing cost can be computed for routine kinds of requests. The form is designed to track all costs and is utilized to compile fee information for the Annual FOIA Report. While not all costs can be charged to the requester for recoupment, they are nonetheless reportable as they provide Congress with an indepth look at the costs and time the Navy is expending to process FOIA requests.

(c) *Scope.* (1) The guidelines set forth below are not intended to imply that fees must be charged for providing information to the public in the routine course of business, nor are they meant as a substitute for any other schedule of

fees, such as those in NAVCOMPTMAN, Vol. 3, CH-339, which does not supersede the collection of fees under FOIA.

(2) Subpart D of this part does not supersede fees chargeable under a statute specifically setting the level of fees for particular types of records. A "statute specifically providing for setting the level of fees for particular types of records" means any statute that enables a government agency, such as the Government Printing Office (GPO) or the National Technical Information Service (NTIS), to set and collect fees. Naval activities should ensure that when documents that would be responsive to a request are maintained for distribution by agencies operating statutory based fee schedule programs such as GPO or NTIS, inform requesters of the steps necessary to obtain records from those sources.

(c) *Resolution of fees.* The issue of fees should be resolved prior to a naval activity expending resources to process a FOIA request. Specifically, a requester should have an opportunity to decide whether or not to pursue a request if fees are applicable and the requester has failed to agree to pay those fees. There have been instances where naval activities have worked a costly request only to be told by the requester that it is no longer needed, since it will result in a cost. Additionally, if a requester has agreed to pay fees up to a specified amount and the costs of processing the request will exceed those fees, naval activities must resolve the issue of additional fees prior to continuing with the processing of the request.

(d) *Responses.* Naval activities shall ensure that final responses to the requester address FOIA fees.

§ 701.41 Definitions.

The following definitions set forth the parameters for determining FOIA fees:

(a) *Direct costs.* Direct costs means those expenditures a naval activity actually incurs in searching for, reviewing (in the case of commercial requesters), and duplicating documents to respond to a FOIA request. Direct costs include, for example, the salary of the employee performing the work (the employee's basic rate of pay plus 16 percent of that rate to cover benefits), and the costs of operating duplicating machinery. Not included are overhead expenses such as costs of space, heating, or lighting the facility where records are stored.

(b) *Search time.* Search time includes all time spent looking for material responsive to a request and a page-by-page or line-by-line identification (if necessary) of material in the document to determine if it, or portions thereof, are responsive to the request. Naval activities should ensure that searches are efficient and completed in the least expensive manner to minimize costs to the naval activity and the requester. For example, naval activities should not do a line-by-line search when duplicating an entire document containing responsive information would be less expensive and quicker to comply with the request. Time spent reviewing documents to determine whether to apply one or more of the statutory exemptions is not search time, but review time.

(c) *Duplication.* Duplication refers to the process of making a copy of a document in response to a FOIA request. Copies can be paper copy, microfiche, audiovisual, or machine readable documentation (e.g., magnetic tape or disc). Every effort will be made to ensure that the copy provided is in a form reasonably usable by requesters. If copies are not clearly usable, the requester will be notified that their copy is the best available and the agency's master copy will be made available for review upon appointment. For duplicating of computer tapes and audiovisuals, the cost, including the operator's time shall be charged. If a naval activity estimates that assessable duplication charges may exceed $25, it shall notify the requester of the estimate, unless the requester has indicated in advance his or her willingness to pay fees as high as those anticipated. Such notice shall offer the requester the opportunity to confer with naval personnel to reformulate the request to meet his or her needs at a lower cost.

(d) *Review.* Review time refers to examining documents responsive to a FOIA request to determine whether one or more of the statutory exemptions permit withholding. It also includes processing the documents for disclosure, such as excising them for release. Review does not include time spent resolving general legal or policy issues on applying the exemptions. Charges may be assessed only for the initial review. Naval activities may not charge for reviews during an administrative appeal of an exemption already applied. Records or portions of records withheld in full under an exemption subsequently determined not to apply, may be reviewed again to determine the applicability of other exemptions not previously considered and the costs for such a subsequent review could be assessed.

(e) *Commercial use request.* A commercial use request is a request from or on behalf of one seeking information for a use or purpose that furthers the commercial, trade, or profit interest of the requester. In determining whether a requester belongs to this category, naval activities must determine the requester's use of the documents requested. Naval activities should seek additional clarification before assigning the request to a specific category when doubting the intended use of the requester, or where the use is not clear from the request itself.

(f) *Educational institution.* An educational institution is a preschool, public or private elementary or secondary school, institution of graduate higher education, institution of undergraduate higher education, institution of professional education, and an institution of vocational education operating a program(s) of scholarly research.

(g) *Non-commercial scientific institution.* A non-commercial scientific institution is operated solely for conducting scientific research the results of which are not intended to promote any particular product or industry and not operated on a "commercial" basis.

(h) *Representative of the news media.* Representative of the new media is a person actively gathering news for an entity organized and operated to publish or broadcast news to the public. "News" means information about current events or of current interest to the public. Examples of news media entities include television or radio station broadcasting to the public at large and publishers of periodicals when qualifying as disseminators of "news" who make their products available for purchase or subscription by the general public. Those examples are not all-inclusive. As traditional methods of news delivery evolve (e.g., electronic dissemination of newspapers through telecommunications services) alternative media would be included in this category. "Free-lance" journalists may be considered as working for a news organization if they can demonstrate a basis for expecting publication by that organization, even if not actually employed. Proof may be by publication contract, but naval activities may also look to the requester's past publication record in making this determination. Representatives of the news media do not include private libraries, private repositories of Government records, or middlemen such as information vendors or data brokers.

(i) *All other requesters.* All other requesters refers to persons who do not qualify as an educational institution, non-commercial scientific institution, representative of the news media, or

commercial use requester. An example is a nonprofit organization.

§ 701.42 Application.

(a) *Commercial requesters.* When records are requested for commercial use, fees shall be assessed to recover reasonable standard charges for document search, review, and duplication. Requesters must reasonably describe the records sought. When naval activities review a request for documents for commercial use, they should assess charges which recover the full direct costs of searching for, reviewing for release, and duplicating the records sought. Commercial requesters, are not entitled to 2 hours of free search time and 100 free pages of reproduction of documents. However, fees totaling $15 or less must be waived. Commercial requesters are not normally entitled to a waiver or reduction of fees based upon an assertion that disclosure would be in the public interest. Because use of the requested material is the exclusive determining criteria, a commercial enterprise may make a request that is not for commercial use. It is also possible that a nonprofit organization could make a request for commercial use. Such situations must be addressed on a case-by-case basis.

(b) *Educational institution requesters.* When a request is made by an educational institution whose purpose is scholarly research fees shall be limited to reasonable standard charges for document duplication (excluding charges for the first 100 pages). Requesters must reasonably describe the records being sought and must show that the request is made under the auspices of a qualifying institution and that the records are not sought for commercial use, but in furtherance of scholarly research.

(c) *Non-commercial scientific institution requesters.* When the request is made by a non-commercial scientific institution whose purpose is scientific research fees shall be limited to only reasonable standard charges for document duplication (excluding charges for the first 100 pages). Requesters must reasonably describe the records sought and must show that the request is being made under the auspices of a qualifying institution and that records are not sought for commercial use, but in furtherance of scientific research.

(d) *Representatives of the news media.* (1) When the request is made by a representative of the news media, fees shall be limited to only reasonable standard charges for document duplication (excluding charges for the first 100 pages). Requesters must reasonably describe the records sought.

(2) Representatives of the news media must meet the criteria defined in paragraph (h) of § 701.41, and the request must not be made for commercial use. A request for records supporting the news dissemination function of the requester shall not be considered to be a request that is for a commercial use. For example, a request by a newspaper for records relating to an investigation of a defendant in a current criminal trial of public interest could be presumed to be a request from an entity eligible for inclusion in this category, and entitled to records at the cost of duplication alone (excluding charges for the first 100 pages).

(3) "Representative of the news media" does not include private libraries, private repositories of Government records, or middlemen, such as information vendors or data brokers.

(e) *All other requesters.* Naval activities shall charge requesters who do not fit into any of the above categories fees to recover the full direct cost of search and duplicating records, except the first 2 hours of search time and the first 100 pages of duplication shall be furnished without charge. Requesters must reasonably describe the records sought. Requests from subjects about themselves will continue to be treated under the fee provisions of 5 U.S.C. 552a, which permit fees only for duplication. Naval activities are reminded that this category of requester may be eligible for a waiver or reduction of fees if disclosure of the information is in the public interest.

§ 701.43 Fee restrictions.

(a) A naval activity may not charge fees if the costs of routine collection and processing of the fee are likely to equal or exceed the amount of the fee. Except for requesters seeking documents for a commercial use, naval activities shall provide the first 2 hours of search time and the first 100 pages of duplication without charge. For example, for a request (other than one from a commercial requester) involving 2 hours and 10 minutes of search time and 105 pages of documents, a naval activity would recover the cost of only ten minutes of search time and five pages of duplication. If this processing cost was equal to or less than the cost to the naval activity for billing the requester and processing the fee collected (i.e., $15), no charges would result.

(b) Requesters are entitled to the first 2 hours of search and 100 pages of duplication without charge once per request. Consequently, if after completing its portion of a request, a naval activity, refers the request to another naval activity to act on their portion of the request, the referring naval activity shall inform the recipient of the amount of search time and duplication cost to date so the final Navy response will address all fees in the processing of the request. For referrals to other federal agencies or Department of Defense components, if the naval costs of processing the request are chargeable based on fee guidelines, the fees should be collected from the requester and the recipient of the referral advised of the fee status of the request. If the fees are not chargeable based on the fee guidelines, the recipient of the referral should be advised of the naval fees associated with the processing of the request.

(c) In determining the "cost of collecting a fee" consider administrative costs to the naval activity of receiving and recording a remittance, and processing the fee for deposit in the Treasury Department's special account. The Treasury's cost to handle such remittance is negligible and shall not be considered in a naval activity's determination.

(d) To determine cost, "pages" refers to standard size paper copies normally 8 1/2" x 11" or 11" x 14". Thus, requesters would not be entitled to 100 microfiche or 100 computer disks, for example. A microfiche containing the equivalent of 100 pages or 100 pages of computer printouts, meets the restriction.

(e) For computer searches, the first 2 free hours will be determined by the salary scale of the individual doing the computer search. For example, when the direct costs of the computer central processing unit, input-output devices, and memory capacity equal $24 (2 hours of equivalent search at the clerical level), computer costs in excess of that amount are chargeable as computer search time.

§ 701.44 Fee waivers.

(a) When the naval activity determines that waiver or reduction of fees is in the public interest, documents will be furnished without charge or at a reduced charge. It is in the public interest when furnishing the information is likely to contribute significantly to public understanding of the operations or activities of the Department of the Navy, and is not primarily in the commercial interest of the requester.

(b) Fees shall be waived automatically for all requesters when direct costs for a FOIA request total $15 or less.

(c) Decisions to waive or reduce fees that exceed the automatic fee waiver threshold shall be made on a case-by-case basis when:

(1) Disclosure of the information "is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government."

(i) Subject of the request. Naval activities should analyze whether the subject matter of the request involves issues which will significantly contribute to the public understanding of the operations or activities of the Department of the Navy. Requests for records in the possession of the Department of the Navy originated by non-government organizations and sought for their intrinsic content rather than informative value will not likely contribute to public understanding of the operations or activities of the Department of the Navy. Examples of such records are press clippings, magazine articles, or records forwarding a particular opinion or concern from a member of the public regarding a naval activity. Similarly, disclosures of records of considerable age may or may not bear directly on the current activities of the Department of the Navy; however, the age of a particular record shall not be the sole criteria for determining the value of a document. These requests must be closely reviewed while considering the requester's stated purpose for the records and the potential for public understanding of the operations and activities of the Department of the Navy.

(ii) Informative value of the information to be disclosed. Naval activities should analyze the substantive contents of a record or portion of the record to determine whether disclosure is meaningful and will inform the public on Department of the Navy's operations or activities. While the subject of a request may contain information on operations or activities of the Department of the Navy, it may not have great potential for contributing to a meaningful understanding of these operations or activities. An example would be a heavily redacted record, with only random words, fragmented sentences, or paragraph headings. A determination as to whether that type of record will contribute to the public understanding of the operations or activities of the Department of the Navy must be weighed against the requester's intended use. Another example is disclosure of information already in the public domain or nearly identical information may add no meaningful new information on Department of the Navy operations and activities.

(iii) Contribution to the public's understanding from disclosure. Disclosure contributes to the public's understanding when disclosure will inform or have the potential to inform the public, rather than the individual requester or small segment of interested persons. The requester's identity determines whether the requester has the capability and intention to disseminate the information to the public. Assertions of plans to write a book, research a particular subject, doctoral desertion work, or indigency are insufficient. Requester must demonstrate the capacity to disclose the information in a manner informative to the general public. Requesters should describe their qualifications, nature of their research, purpose of the requested information, and intended means of dissemination to the public.

(iv) The significance of the contribution to public understanding. Naval activities must assess the significance or impact of disclosure against the current level of public knowledge or understanding prior to the disclosure. In other words, will disclosure on a current subject of wide public interest be unique in contributing previous unknown facts, thereby enhancing public knowledge, or will it basically duplicate what is already known by the general public. Naval activities shall not make value judgments whether the information is important enough to be made public.

(2) Disclosure of the information "is not primarily in the commercial interest of the requester."

(i) Existence and magnitude of a commercial interest. If the request is a commercial interest, naval activities should address the magnitude of that interest to see if the requester's commercial interest is primary, as opposed to any secondary personal or non-commercial interest. In addition to profit-making organizations, individual persons or other organizations may have a commercial interest in obtaining certain records. Where it is difficult to determine whether this is a commercial requester, naval activities may infer it from the requester's identity and circumstances of the request. The requester's commercial benefit must clearly override any personal or nonprofit interest to apply FOIA commercial standards.

(ii) The primary interest in disclosure. Once a requester's commercial interest has been determined, naval activities should then determine if disclosure would be primarily in that interest. That requires balancing the commercial interest of the request against any public benefit derived as a result of that disclosure. Where the public interest served is beyond that of the requester's commercial interest, a waiver or reduction of fees would be appropriate. Conversely, even if a significant public interest exists and the relative commercial interest of the requester is greater than the public interest, then a waiver or reduction of fees would be inappropriate. For example, while news media organizations have a commercial interest as business organizations, their role of disseminating news to the public can ordinarily be presumed to be of a primary interest. Therefore, any commercial interest is secondary to the primary interest in serving the public. Similarly, scholars writing books or engaged in other forms of academic research may recognize a commercial benefit, either directly or indirectly (through the institution they represent); however, normally such pursuits are primarily undertaken for educational purposes, and charging a fee would be inappropriate. Conversely, data brokers or others who compile government information for marketing can normally be presumed to primarily have a commercial interest.

(iii) The above factors and examples are not all inclusive. Each fee decision must be considered on a case-by-case basis the merits of the information provided in each request. When the decision to charge, reduce, or waive the fee cannot be clearly resolved, naval activities should rule in favor of the requester.

(d) The following additional circumstances describe situations where waiver or reduction of fees are most likely warranted:

(1) A record is voluntarily created to preclude an otherwise burdensome effort to provide voluminous amounts of available records, including additional information not requested.

(2) A previous denial of records is reversed in total, or in part, and the assessable costs are not substantial (e.g., $15 - $30).

§ 701.45 Fee assessment.

(a) Fees may not be used to discourage requesters. FOIA fees are limited to standard charges for direct document search, review (in the case of commercial requesters), and duplication.

(b) To be responsive as possible to FOIA requests while minimizing unwarranted costs to the taxpayer, naval activities shall:

(1) Analyze each request to determine the category of the requester. If the

naval activity's determination of the category of the requester is different than that claimed by the requester, the naval activity will:

(i) Notify the requester that additional justification should be provided to support the category claimed, and that a search for responsive records will not be initiated until agreement on the category of the requester. Absent further category justification from the requester and a reasonable period of time (i.e., 30 calendar days), the naval activity shall render a final category determination and notify the requester of the determination, including administrative appeal rights.

(ii) Advise the requester that a search for responsive records will not be initiated until the requester indicates a willingness to pay assessable costs for the category determined by the naval activity.

(2) Requesters must submit a fee declaration appropriate for these categories:

(i) Commercial requesters must indicate a willingness to pay all search, review, and duplication costs.

(ii) Educational or non-commercial scientific institution or news media representatives. Requesters must indicate a willingness to pay duplication charges in excess of 100 pages, if more than 100 pages of records are desired.

(iii) All others. Requesters must indicate a willingness to pay assessable search and duplication costs if more than 2 hours of search effort or 100 pages of records are desired and the resultant fees will exceed the $15 fee waiver threshold.

(3) If the above conditions are not met, then the request need not be processed and the requester shall be so informed within 10 working days.

(4) As described above, naval activities must be prepared to provide an estimate of assessable fees to the requester. While searches vary among naval activities and an estimate is often difficult prior to an actual search, requesters desiring estimates are entitled to them before committing to a willingness to pay. Should naval activity costs exceed the amount of the estimate or the amount agreed to by the requester, the amount in excess of the estimate or the amount agreed to shall not be charged without the requester's agreement.

(5) A naval activity may not require advance payment of any fee (i.e., payment before work is commenced or continued on a request) unless the requester previously failed to timely pay fees or the agency determined that the fee exceeds $250. A timely fashion is 30 calendar days from the date of billing by the naval activity.

(6) Where a naval activity estimates or determines that allowable charges that a requester may be required to pay are likely to exceed $250, the naval activity should notify the requester of the likely cost and obtain satisfactory assurance of full payment where the requester has a history of prompt payments, or require an advance payment of an amount up to the full estimated charges for requesters without a history of payment.

(7) Where a requester has previously failed to pay a fee charged in a timely fashion (i.e., within 30 calendar days from the date of the billing), the naval activity may require the requester to pay the full amount owed, plus any applicable interest, or demonstrate that the fee had been paid, and to make an advance payment of the full amount of the estimated fee before the naval activity begins to process a new or pending request. Interest will be at the rate prescribed in 31 U.S.C. 3717 and confirmed with respective accounting and finance offices.

(8) After all work is completed on a request and the documents are ready for release, naval activities may request payment prior to forwarding the documents if there is no payment history on the requester or if the requester has previously failed to pay a fee in a timely fashion (i.e., within 30 calendar days of the billing). If the requester fails to pay in a timely fashion, paragraph (b)(7) of § 701.45 applies. Naval activities may not hold documents ready for release pending payment from requesters with a history of prompt payment.

(9) When naval activities act under § 701.45 number (b)(1) through (7), FOIA time limits (10 working days from receipt of initial requests and 20 working days from receipt of appeals, plus permissible extensions of time) begin after the naval activity has received a willingness to pay fees or fee payments, if appropriate.

(10) Naval activities may charge for time spent in searching for records, even if that search fails to locate records responsive to the request. Naval activities may also charge search and review (in the case of commercial requesters) time if records located are determined to be exempt from disclosure. In practice, if the naval activity estimates that search charges are likely to exceed $25, it shall notify the requester of the estimated amount of fees, unless the requester has indicated in advance a willingness to pay fees up to the estimated amount. Such notice shall offer the requester the opportunity to confer with the naval activity with the object of reformulating the request to meet his or her needs at a lower cost.

§ 701.46 Aggregating requests.

Except for commercial requesters, a naval activity may not charge for the first 2 hours of search time or for the first 100 pages of reproduction. A requester may not file multiple requests at the same time each seeking portions of a document or documents to avoid payment of fees. When a naval activity reasonably believes that a requester or, a group of requesters acting in concert is attempting to break a request into a series of requests to evade fees, the naval activity may aggregate the requests and charge accordingly. In determining whether it is reasonable to aggregate the requests, consider the time period of the requests. For example, it would be reasonable to presume that multiple requests of this type made within a 30-day period had been made to avoid fees. It is harder to make that presumption for requests over a longer time period. Before aggregating requests from more than one requester, naval activities must have a concrete basis to conclude that the requesters are acting in concert to avoid payment of fees. Naval activities may not aggregate multiple requests from one requester on unrelated subjects.

§ 701.47 Effect of the Debt Collection Act of 1982 (Pub. L. 97-365).

The Debt Collection Act of 1982 (Pub. L. 97-365) provides for a minimum annual rate of interest on overdue debts to the Federal Government. Naval activities may charge an interest penalty for fees outstanding 30 days from the date of billing (the first demand notice). The interest rate shall be as prescribed in 31 U.S.C. 3717. Naval activities should verify the current interest rate with respective accounting and finance offices. After one demand letter has been sent and 30 calendar days have lapsed with no payment, naval activities may submit the debt to the respective accounting and finance offices for collection under the Debt Collection Act of 1982.

§ 701.48 Computation of fees.

The fee schedule in Subpart D of this part shall be used to compute search, review (in the case of commercial requesters), and duplication costs for processing FOIA requests. Costs shall be computed on time actually spent. Time-based and dollar-based minimum charges for search, review (in the case of commercial requesters), and duplication are not authorized.

§ 701.49 Collection of fees.

Collect FOIA fees when providing the documents to the requester when the requester specifically states that costs are acceptable or acceptable up to a specified amount. Collection may not be made in advance unless the requester has failed to pay previously assessed fees within 30 calendar days from the date of the billing by the naval activity, or the naval activity determines the fee will be in excess of $250.

§ 701.50 Search time costs.

The following schedules outline authorized fees:

(a) *Manual search.*

Type	Grade	Hourly Rate
Clerical	E9/GS8 and below	$12
Professional	01-06/GS9-GS/GM15	25
Executive	07/GS/GM16/ES1 and above.	45

(b) *Computer search.* Computer search is based on the direct cost of the central processing unit, input-output devices, and memory capacity of the computer configuration. The cost of computer search is based on the computer operator/programmer's time in determining how to conduct and subsequently executing the search and is charged at the rate of a manual search.

(c) *Duplication costs.*

Type	Cost per Page
Pre-printed material (i.e., unaltered directives, publications)	$.02
Office copy (i.e., xeroxed copies)	.15
Microfiche	.25
Computer copies (tapes or reprints)	Actual cost [1]

[1] This means the cost of duplicating the tape or printout, which includes the operator's time and cost of the tape.

(d) *Review time (only applies in the case of commercial requesters).*

Type	Grade	Hourly Rate
Clerical	E9/GS8 and below	$12
Professional	01-06/GS9-GS/GM15	25
Executive	07/GS/GM16/ES1 and above.	45

(e) *Audiovisual documentary materials.* Compute search costs as for any other record. Duplication cost is the actual direct cost of reproducing the material, including the wage of the person doing the work. Audiovisual materials provided to a requester need not be in reproducible format or quality.

(f) *Other records.* Compute direct search and duplication cost for any record not described above as described for audiovisual documentary material.

(g) *Costs for special services.* Complying with requests for special services is at the discretion of the naval activity. FOIA and its fee structure do not cover these kinds of services. Naval activities may recover the costs of special services asked for by the requester after agreement has been obtained from the requester to pay for one or more of the following services:

(1) Certifying that records are true copies.

(2) Sending records by special methods such as express mail, etc.

§ 701.51 FOIA fee remittance/receipt controls.

(a) Naval activities shall implement procedures to track FOIA fee remittances. At a minimum, the tracking system should include the name of the requester, company (if applicable), amount of fee charged (identify by total and breakdown, i.e., $250: $100 search, $50.00 review, $100 reproduction), date and serial number of correspondence to the requester which seeks the fee remittance, date remittance received, number of check, date sent to local disbursing office, and copy of NAVCOMPT Form 2277. This tracking system can be manual or automated and should be designed to identify outstanding FOIA remittances so that follow-up letters can be sent advising the requester that his/her account requires prompt action.

(b) Naval activities shall advise requesters to make their check/money order payable to the Treasurer of the United States. Upon receipt of a check/money order, the receiving activity shall submit a NAVCOMPT Form 2277, Voucher for Disbursement and/or Collection, and the check/money order to the local disbursing office for processing. "FOIA Receipt Account Number 3210" shall be annotated on the NAVCOMPT Form 2277 when processing all FOIA fees, except those received by naval industrially-funded (NIF) and non-appropriated funded (NAF) activities.

(c) Remittances received by NIF activities shall be made payable to the activity and the requester should indicate on the check "FOIA Remittance." The remittance shall be deposited in the NIF activity account.

(d) Remittances received by NAF activities shall be made payable to the activity and the requester should indicate on the check "FOIA Remittance." The remittance shall be deposited in the NAF activity account.

§ 701.52 Technical data fees.

(a) *General.* Technical data, recorded information, regardless of the form or method of the recording, of a scientific or technical nature (including computer software documentation). This term does not include computer software or data incidental to contract administration, such as financial and/or management information. Technical data requiring release under FOIA, shall be released after the requester pays all reasonable costs for search, duplication, and review of the records to be released.

(b) *Definition.* Technical data means recorded information, regardless of the form of method of the recording of a scientific or technical nature (including computer software documentation). This term does not include computer software or data incidental to contract administration, such as financial and/or management information.

(c) *Retention of funds.* Naval activities shall retain fees received from releasing technical data. The funds shall be available for the same purpose and the same time period as the appropriation from which the costs were incurred in complying with the request. Reasonable costs are the full costs to the Government of rendering the service, or fair market value of the service, whichever is greater. Fair market value shall be determined by commercial rates in the local geographical area. In the absence of a known market value, charges shall be based on recovery of full costs to the Government. The full cost includes all direct and indirect costs to conduct the search and to duplicate records responsive to the request. This cost is different from the direct costs allowable under the FOIA.

(d) *Waiver.* Naval activities shall waive the payment of costs for technical data when greater than the costs required for release of this same information under FOIA, if:

(1) The request is made by a United States citizen or a United States corporation who certifies that the technical data requested is needed to submit an offer, or determine capability

of submitting an offer. The technical data must relate to the product which will be provided to the United States or a contractor with the United States. However, naval activities may require the citizen or corporation to pay a deposit of not more than the cost of complying with the request, which will be refunded upon submission of an offer by the citizen or corporation;

(2) The release of technical data is requested to comply with an international agreement; or,

(3) The naval activity determines that waiver is in the interest of the United States.

(e) *Fee rates.* (1) Search time is computed as follows:

(i) Manual Search.

Type	Grade	Hourly Rate
Clerical	E9/GS8 and below	$13.25
(Minimum Charge).		8.30

Professional and Executive hourly rate of fees are established at actual hourly rate prior to search. A minimum charge will be established at 1/2-hourly rates.

(ii) Computer search is the total cost of the central processing unit, input-output devices, and memory capacity of the actual computer configuration. The wage for the computer analyst/operator determining how to conduct and subsequently executing the search will be recorded as part of the computer search and is at the same rate of the manual search scale.

(2) Duplication costs are as follows:

Type	Cost
Aerial photographs, specifications, permits, charts, blue prints, and other technical documents	$2.50 each
Engineering data (microfilm):	
Aperture cards:	
Silver duplicate negative	$.75 per card
(When keypunched and verified)	.85 per card
Diazo duplicate negative	.65 per card
(When keypunched and verified)	.75 per card
35mm roll film	$.50 per frame
16mm roll film	.45 per frame
Paper prints (engineering drawings)	$1.50 each
Paper reprints of microfilm indices	.10 each

(3) Review time is computed as follows:

Type	Grade	Hourly Rate
Clerical	E9/GS8 and below	$13.25
(Minimum Charge).		8.30

Professional and Executive hourly rate of fees are established at actual hourly rate prior to review. A minimum charge will be established at 1/2-hourly rates.

§ 701.53 Other technical data records.

Charges for services not specifically provided above are at the following rates:

Type	Cost
Minimum charge for office copy (up to six images)	$3.50
Each additional image	.10
Each typewritten page	3.50
Certification and validation with seal	5.20
Hand-drawn plots and sketches, each hour or fraction thereof	12.00

Dated: December 18, 1991.

Wayne T. Baucino,

Lieutenant, JAGC, U.S. Naval Reserve, Alternate Federal Register Liaison Officer.

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CCGD13 91-06]

Drawbridge Operation Regulations; Umpqua River, OR

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: At the request of the Oregon Department of Transportation (ORDOT), the Coast Guard is changing the regulations governing the U.S. 101 highway bridge across the Umpqua River, mile 11.1, at Reedsport, Oregon. This change requires that at least two hour's advance notice be given for opening the drawspan of this bridge at all times for the passage of vessels. This amendment is being made because of a marked decrease in requests for bridge openings. This regulation change should relieve the bridge owner of the burden of having a person constantly available to open the draw while still providing for the reasonable needs of navigation.

EFFECTIVE DATE: This regulation change becomes effective on January 23, 1992.

FOR FURTHER INFORMATION CONTACT: John E. Mikesell, Chief, Bridge Section, Aids to Navigation and Waterways Management Branch (Telephone: (206) 553-5864).

SUPPLEMENTARY INFORMATION: On September 23, 1991, the Coast Guard published a proposed rule (56 FR 47932) concerning the amendment. The Commander, Thirteenth Coast Guard District, also published the proposal as a public notice dated September 30, 1991. In each notice interested persons were given until November 7, 1991, to submit comments.

Drafting Information

The drafters of this notice are: Austin Pratt, project officer, and Lieutenant Deborah K. Schram, project attorney.

Discussion of the Comments

No objections to the proposed rule change were received.

Federalism

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that the rulemaking does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Economic Assessment and Certification

The regulations are considered to be non-major under Executive Order 12291 on Federal Regulation and nonsignificant under the Department of Transportation regulatory policies and procedures (44 FR 11034; February 26, 1979). The economic impact of this rule change is expected to be so minimal that a full regulatory evaluation is unnecessary. Navigation and marine-related businesses would not be significantly affected by this action because the present trend of infrequent drawspan openings is expected to continue into the future. Since the economic impact of this regulation change is expected to be minimal, the Coast Guard certifies that it will not have a significant impact on a substantial number of small entities.

Environmental Impact

This action has been reviewed by the Coast Guard and has been determined to be categorically excluded from further environmental documentation in accordance with paragraph 2.B.2.g.(5) of the NEPA Implementing Procedures COMDTINST M16475.1B. A Categorical Exclusion Determination is available in

the docket for inspection or copying where indicated under **ADDRESSES.**

List of Subjects in 33 CFR Part 117

Bridges.

Regulations

In consideration of the foregoing, part 117 of 33, Code of Federal Regulations is amended as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 49 CFR 1.46; 33 CFR 1.05–1(g).

2. Section 117.893 is amended by revising paragraph (a) to read as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

§ 117.893 Umpqua River

(a) The draw of the US 101 Bridge, mile 11.1, at Reedsport, Oregon, shall open on signal if at least two hours notice is given.

* * * * *

Dated: December 9, 1991.

J.E. Vorbach,

Rear Admiral, U.S. Coast Guard, Commander, 13th Coast Guard District.

[FR Doc. 91–30701 Filed 12–23–91; 8:45 am]

BILLING CODE 4910-14-M

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33 CFR Part 165

[COTP Port Arthur, Texas Regulation 90-03]

Safety Zone Regulations; Calcasieu Channel and Industrial Canal, Calcasieu River, Lake Charles, LA

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: The Coast Guard is revising the existing safety zone in the turning basin of the Industrial Canal, Calcasieu River, Lake Charles, LA. The safety zone is necessary to safeguard vessels, personnel and property against the accidental release of liquefied natural gas (LNG) at the Trunkline LNG Terminal. Revising the existing safety zone will accurately reflect the hazardous areas of the turning basin and ensure public safety while allowing the public to continue to fish in one of the prime fishing areas in the Calcasieu River.

EFFECTIVE DATE: January 23, 1992.

FOR FURTHER INFORMATION CONTACT: LCDR Gilbert Kanazawa, Supervisor, MSD Lake Charles, LA at (318) 433–3765 or FTS: 687–7226.

SUPPLEMENTARY INFORMATION: On August 2, 1991, the Coast Guard published a notice of proposed rule making in the **Federal Register** for these regulations (Vol. 56 No. 149 FR page 37052). Interested persons were requested to submit comments and no comments were received.

Drafting Information

The drafters of these regulations are Lieutenant Commander Gilbert Kanazawa and Lieutenant Junior Grade Gary Messmer, project officers for the Captain of the Port and Lieutenant Wilson, Project Attorney, Eighth Coast Guard District Legal Office, New Orleans, Louisiana.

Discussion of Comments

The Coast Guard did not receive any comments on the revision of the safety zone.

Economic Assessment and Certification

These regulations are considered to be non-major under Executive Order 12291 on Federal Regulation and nonsignificant under Department of Transportation regulatory policies and procedures (44 FR 11034; February 26, 1979). The economic impact of this proposal is expected to be so minimal that a full regulatory evaluation is unnecessary. The users of the Port of Lake Charles fall into four main categories; Commercial Shipping, Commercial Fishing Vessels, Small Passenger Boats and Pleasure Boats. Since this zone is actually reducing the area encompassed in an already existing safety zone, there should be no adverse impact on harbor use. Since the impact of this proposal is expected to be minimal, the Coast Guard certifies that, if adopted, it will not have a significant economic impact on a substantial number of small entities.

Federalism

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Vessels, Waterways.

Final Regulations

In consideration of the foregoing part 165 of Title 33, Code of Federal Regulations, is amended as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 49 CFR 1.46 and 33 CFR 1.05–1(g), 6.04–1, 6.04–6 and 160.5.

2. Section 165.805, paragraph (a) is revised to read as follows:

§ 165.805 Calcasieu Channel and Industrial Canal, Calcasieu River, Lake Charles, LA

(a) The waters and waterfront facility located within the area described by the following boundaries constitutes a safety zone:

(1) When a Liquefied Natural Gas (LNG) vessel is moored at Trunkline LNG facility: Beginning at the west side property line at position 30 06'38"N, 93 17'34"W, a line extending in an eastward direction and 50 feet from shore to a point 50 feet west of mooring dolphin #1, then due south to a line running in an eastward direction and 50 feet south of the moored LNG vessel to a line running due north to a point 50 feet east of mooring dolphin #13; and then a line extending in an eastward direction and 50 feet from shore to the end of the turning basin.

(2) When an LNG vessel is not moored at the Trunkline LNG facility: Beginning at the west side property line at position 30 06'38"N, 93 17'34"W, a line extending in an eastward direction and 50 feet from shore to a point 50 feet west of mooring dolphin #1, then a continuous uniform line extending 50 feet outside of all facility docks and structures to a point 50 feet east of mooring dolphin #13; and then a line extending in an eastward direction and 50 feet from shore to the end of the turning basin.

* * * * *

Dated: 12 December 1991.

J.L. Robinson,

Captain, U.S. Coast Guard, Captain of the Port, Port Arthur, TX.

[FR Doc. 91–30702 Filed 12–23–91, 8:45 am]

BILLING CODE 4910-14-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 81

[NC–053; FRL–4086–2]

Designation of Areas for Air Quality Planning Purposes; North Carolina: Redefinition of Attainment Areas From Statewide to County-by-County

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA today approves revisions to 40 CFR part 81 for North Carolina. EPA today is changing the description of NO_2 attainment areas in the State of North Carolina at the request of the Department of Environment, Health and Natural Resources. Attainment status designations included in 40 CFR 81.334 will now be listed on a county-by-county basis rather than under the generally inclusive term "Statewide". This change is anticipated to make it easier for North Carolina to track increment consumption in connection with prevention of significant deterioration of air quality.

EFFECTIVE DATE: This action will be effective February 24, 1992, unless notice is received within 30 days that someone wishes to submit adverse or critical comments. If the effective date is delayed, timely notice will be published in the **Federal Register**.

ADDRESSES: Copies of the material submitted by North Carolina may be examined during normal business hours at the following locations:

Region IV Air Programs Branch, Environmental Protection Agency, 345 Courtland Street, Atlanta, Georgia 30365;

Department of Environment, Health, and Natural Resources, Division of Environmental Management, 512 North Salisbury St., Raleigh, North Carolina 27604.

FOR FURTHER INFORMATION CONTACT: Benjamin Franco of the EPA Region IV Air Programs Branch at 404–347–2864 (FTS–257–2864) and at the above address.

SUPPLEMENTARY INFORMATION: On August 13, 1991, the North Carolina Department of Environment, Health and Natural Resources submitted a request for an amendment to 40 CFR 81.334. This amendment will provide a listing for NO_2 attainment status on a county-by-county basis rather than under the generally inclusive term "Statewide". This redefinition of attainment areas will make it easier for North Carolina to track increment consumption in connection with the prevention of significant deterioration of air quality. Prior to this redefinition, the first permit application filed within "Statewide" could trigger a baseline air quality determination for the entire state. Listing attainment areas on a county-by-county basis in 40 CFR 81.334 will allow baseline dates to be triggered separately for individual counties and will therefore, not restrict growth unnecessarily.

Since this notice simply redefines attainment areas on a county-by-county basis, no areas are being redesignated by this action.

Final Action

EPA is today approving the revision to 40 CFR 81.334. This action is being taken without prior proposal because the changes are noncontroversial and EPA anticipates no significant comments on them. The public should be advised that this action will be effective February 24, 1992. However, if notice is received within 30 days that someone wishes to submit adverse or critical comments, this action will be withdrawn and two subsequent notices will be published before the effective date. One notice will withdraw the final action and another will begin a new rulemaking by announcing a proposal of the action and establishing a comment period.

Under section 307(b)(1) of the Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by February 24, 1992. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. [See section 307(b)(2).]

Under 5 U.S.C. 605(b), the Administrator has certified that redesignations do not have a significant economic impact on a substantial number of small entities. (See 46 FR 8709.)

This action has been classified as a Table (3) action by the Regional Administrator under the procedures published in the **Federal Register** on January 19, 1989 (54 FR 2214–2225). The Office of Management and Budget waived Table 2 and 3 SIP revisions (54 FR 2222) from the requirements of section 3 of Executive Order 12291 for a period of two years. EPA has submitted a request for a permanent waiver for Table 2 and 3 revisions. OMB has agreed to continue the temporary waiver until such time as it rules on EPA's request.

List of Subjects in 40 CFR Part 81

Air pollution control, National parks, Wilderness areas.

Authority: 42 U.S.C. 7401–7642.

Dated: December 9, 1991.

Patrick M. Tobin,

Acting Regional Administrator.

Part 81 of chapter I, title 40, Code of Federal Regulations, is amended as follows:

PART 81—[AMENDED]

1. The authority citation for part 81 continues to read as follows:

Authority: 42 U.S.C. 7401–7642.

Subpart C—Section 107 Attainment Status Designations

2. Section 81.334, is amended by revising the attainment status designation table "North Carolina—NO_2" to read as follows:

§ 81.334 North Carolina.

* * * * *

NORTH CAROLINA—NO_2

Designated areas	Does not meet primary standards	Cannot be classified or better than national standards
Alamance County		X
Alexander County		X
Alleghany County		X
Anson County		X
Ashe County		X
Avery County		X
Beaufort County		X
Bertie County		X
Bladen County		X
Brunswick County.		X
Buncombe County.		X
Burke County		X
Cabarrus County		X
Caldwell County		X
Camden County		X
Carteret County		X
Caswell County		X
Catawba County		X
Chatham County		X
Cherokee County		X
Chowan County		X
Clay County		X
Cleveland County		X
Columbus County		X
Craven County		X
Cumberland County.		X
Currituck County		X
Dare County		X
Davidson County		X
Davie County		X
Duplin County		X
Durham County		X
Edgecombe County.		X
Forsyth County		X
Franklin County		X
Gaston County		X
Gates County		X
Graham County		X
Granville County		X
Greene County		X
Guilford County		X
Halifax County		X
Harnett County		X

NORTH CAROLINA—NO_2—Continued

Designated areas	Does not meet primary standards	Cannot be classified or better than national standards
Haywood County		X
Henderson County.		X
Hertford County		X
Hoke County		X
Hyde County		X
Iredell County		X
Jackson County		X
Jones County		X
Lee County		X
Lenoir County		X
Lincoln County		X
McDowell County		X
Macon County		X
Madison County		X
Martin County		X
Mecklenburg County.		X
Mitchell County		X
Montgomery County.		X
Moore County		X
Nash County		X
New Hanover County.		X
Northampton County.		X
Onslow County		X
Orange County		X
Pamlico County		X
Pasquotank County.		X
Pender County		X
Perquimans County.		X
Person County		X
Pitt County		X
Polk County		X
Randolph County		X
Richmond County		X
Robeson County		X
Rockingham County.		X
Rowan County		X
Rutherford County.		X
Sampson County		X
Scotland County		X
Stanly County		X
Stokes County		X
Surry County		X
Swain County		X
Transylvania County.		X
Tyrrell County		X
Union County		X
Vance County		X
Wake County		X
Warren County		X
Washington County.		X
Watauga County		X
Wayne County		X
Wilkes County		X
Wilson County		X

[FR Doc. 91-30584 Filed 12-23-91; 8:45 am]

BILLING CODE 6560-50-M

40 CFR Part 300

[FRL 4037-4]

National Oil and Hazardous Substances Pollution Contingency Plan; Deletion of Sites From the National Priorities List; Five-Year Reviews

AGENCY: Environmental Protection Agency.

ACTION: Notice of policy change.

SUMMARY: The Environmental Protection Agency (EPA) is today revising its policy with respect to the deletion of sites from the National Priorities List (NPL) under the Comprehensive Environmental Response, Compensation, and Liability Act, as amended (CERCLA). Agency policy had linked deletion from the NPL with the "five-year reviews" conducted pursuant to section 121(c) of CERCLA. EPA has now determined that the two processes (deletion and five-year review) should be managed separately.

EFFECTIVE DATE: December 24, 1991.

FOR FURTHER INFORMATION CONTACT: Murray Newton, Chief, State and Local Coordination Branch, Office of Emergency and Remedial Response, OS-22OW, U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460 at (703) 308-8380 or the RCRA/Superfund Hotline from 8:30 a.m. to 7:30 p.m., Monday-Friday, toll free at 1-(800)-424-9346 or in Washington, DC at 382-3000.

SUPPLEMENTARY INFORMATION: EPA initiates the deletion process for a National Priorities List (NPL) site only after the Agency determines that no further response action is necessary (other than operation and maintenance of the remedy). Moreover, although the Comprehensive Environmental Response, Compensation, and Liability Act, as amended (CERCLA), provides neither criteria nor a procedure for deletions, EPA has imposed upon itself a careful and fully documented process for deleting sites from the NPL. See National Contingency Plan (NCP), 40 CFR 300.425(e).

CERCLA section 121(c) mandates that the Administrator review the remedial action taken at certain sites "no less often than each 5 years after initiation of such action to assure that human health and the environment are being protected by the remedial action being implemented." This "five-year review" requirement is separate from, and unaffected by, the deletion process; that is, since section 121(c) makes no reference to either the NPL or to deletion from it, sites requiring five-year review must have that review regardless of whether they are still on the NPL.

In early 1989, the Administrator directed a comprehensive review of the Superfund program, subsequently published in June 1989 as "A Management Review of the Superfund Program," also referred to as the Superfund Management Review (SMR). The SMR included many recommendations, one of which was that EPA modify its deletion process such that no site would be deleted from the NPL until at least one "five-year review" had been conducted at the site following final cleanup. This recommendation was integrated into Agency policy in the preamble to the NCP (55 FR 8666, 8699; March 8, 1990).

Subsequent experience and analysis, however, have shown EPA that tying these two independent processes (five-year review and NPL deletion) is unnecessary and potentially confusing. The policy requires EPA to retain sites on the NPL which are otherwise eligible to be deleted, but which stay on the list solely because they await a five-year review after completion of response action. EPA is concerned that keeping on the NPL sites at which no further response action is necessary invites confusion about the meaning and importance of the NPL. It is also unnecessary in terms of ensuring protectiveness. Where there is "a significant release" at a deleted site, the site may be restored to the NPL "without application of the hazard ranking system." See CERCLA section 105(e) and 40 CFR 300.425(e)(3) (55 FR 8846; March 8, 1990). Consequently, the Agency has determined that the public is better served by de-linking these two processes.

The Agency's decision to return to the previous policy in no way compromises or diminishes the protection CERCLA affords the public health and environment, since all sites requiring five-year reviews will receive them. Further, in order to ensure that the public knows which sites require five-year reviews, EPA intends to create and publish a "monitoring list" which identifies such sites regardless of whether they are on the NPL or have been remediated and deleted from it.

Accordingly, effective immediately, EPA may delete sites from the NPL when applicable deletion criteria have been satisfied, and will not retain sites in the NPL solely because they are subject to five-year review.

Dated: November 22, 1991.

William K. Reilly,

Administrator, Office of Solid Waste and Emergency Response.

[FR Doc. 91-30582 Filed 12-23-91; 8:45 am]

BILLING CODE 6560-50-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Public Land Order 6917

[OR-943-4214-10; GP2-018; ORE-03644]

Partial Revocation of the Bureau of Land Management Order Dated January 24, 1956; Oregon

AGENCY: Bureau of Land Management, Interior.

ACTION: Public land order.

SUMMARY: This order revokes a Bureau of Land Management order insofar as it affects 40 acres of public land withdrawn for Bureau of Reclamation's Rogue River Basin Project. The land is no longer needed for reclamation purposes. The revocation is needed to permit disposal of the land through land exchange under section 206 of the Federal Land Policy and Management Act of 1976. This action will open the land to surface entry and mining subject to other segregations of record. The land has been and will remain open to mineral leasing.

EFFECTIVE DATE: January 23, 1992.

FOR FURTHER INFORMATION CONTACT: Linda Sullivan, BLM Oregon State Office, P.O. Box 2965, Portland, Oregon 97208, 503-280-7171.

By virtue of the authority vested in the Secretary of the Interior by section 204 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714 (1988), it is ordered as follows:

1. Bureau of Land Management Order dated January 24, 1956, which withdrew public land for reclamation project purposes, is hereby revoked insofar as it affects the following described land:

Willamette Meridian

T. 35 S., R. 6 W.,
Sec. 14, NW¼SE¼.

The area described contains 40 acres in Josephine County.

2. At 8:30 a.m., on January 23, 1992, the land will be opened to the operation of the public land laws generally, subject to valid existing rights, the provisions of existing withdrawals, other segregations of record, and the requirements of applicable law. All valid applications received at or prior to 8:30 a.m., on January 23, 1992 shall be considered as simultaneously filed at that time. Those received thereafter shall be considered in the order of filing.

3. At 8:30 a.m., on January 23, 1992, the land will be opened to location and entry under the United States mining laws, subject to valid existing rights, the provisions of existing withdrawals, other segregations of record, and the requirements of applicable law. Appropriation of any of the land described in this order under the general mining laws prior to the date and time of restoration is unauthorized. Any such attempted appropriation, including attempted adverse possession under 30 U.S.C. 38 (1988), shall vest no rights against the United States. Acts required to establish a location and to initiate a right of possession are governed by State law where not in conflict with Federal law. The Bureau of Land Management will not intervene in disputes between rival locators over possessory rights since Congress has provided for such determinations in local courts.

Dated: December 13, 1991.

Dave O' Neal,

Assistant Secretary of the Interior.

[FR Doc. 91-30650 Filed 12-23-91; 8:45 am]

BILLING CODE 4310-33-M

43 CFR Public Land Order 6918

[OR-943-4214-10; GP2-036; OR-44954]

Public Land Order No. 6880, Correction; Withdrawal of National Forest System Lands for Pringle Falls Experimental Forest and Research Natural Area; Oregon

AGENCY: Bureau of Land Management, Interior.

ACTION: Public Land Order.

SUMMARY: This order will correct the error in the land description in Public Land Order No. 6880.

FOR FURTHER INFORMATION CONTACT: Linda Sullivan, BLM Oregon State Office, P.O. Box 2965, Portland, Oregon 97208, 503-280-7171.

By virtue of the authority vested in the Secretary of the Interior by section 204 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714 (1988), it is ordered as follows:

The land description in Public Land Order No. 6880, 56 FR 49416, September 30, 1991, is hereby corrected as follows:

The land description reads "T. 21 SW., R. 9 E.," and is hereby corrected to read "T. 21 S., R. 9 E.,".

Dated: December 13, 1991.

Dave O'Neal,

Assistant Secretary of the Interior.

[FR Doc. 91-30654 Filed 12-23-91; 8:45 am]

BILLING CODE 4310-33-M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 61

[CC Docket No. 90-132, FCC No. 91-390]

Competition in the Interstate Interexchange Marketplace

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Memorandum Opinion and Order revises the cut-off date for the grandfathering of Tariff 12 options with inbound service to include Tariff 12 options filed before September 1, 1991. The effect of this order will be to benefit consumers who had completed or substantially completed negotiations for Tariff 12 options with inbound service prior to August 1, 1991.

EFFECTIVE DATE: November 25, 1991.

FOR FURTHER INFORMATION CONTACT: Andy Lachance, (202) 632-4047, Policy and Program Planning Division, Common Carrier Bureau.

SUPPLEMENTARY INFORMATION: On August 1, 1991, we adopted Report and Order in this docket that modified certain of our regulations and policies to reflect the growth of competition in the interstate interexchange marketplace (56 FR 55235, October 25, 1991). We there found, *inter alia*, that the lack of 800 number portability is an impediment to full competition in 800 services and that AT&T may have the ability to leverage market power in 800 or inbound services in order to gain an advantage in the provision of other services. Accordingly, we prohibited AT&T from including in contract-based tariffs and future Tariff 12 options any 800 service or inbound component. However, in light of our order in the 800 access proceeding limiting the lack of 800 number portability to approximately 18 months, and in order to avoid serious customer dislocation, we decided to grandfather Tariff 12 options on file as of August 1, 1991, and to require AT&T to permit customers to terminate these packages without termination liabilities at the time that 800 numbers became portable.

In the week following our adoption of the Report and Order, AT&T filed 15 additional Tariff 12 options. Each of these options contains an inbound

component in violation of the prohibition adopted in our Report and Order.

Upon reconsideration, we find that the public interest will be served by revising the grandfathering date to include Tariff 12 options that contain inbound service filed before September 1, 1991. In adopting August 1, 1991, as the cut-off date for the grandfathering provision in the Report and Order, we sought to establish a date that would not be arbitrary by requiring us to evaluate the status of negotiations or the relative burdens of renegotiations for Tariff 12 options that were not filed by that date. We were also concerned that allowing AT&T a window of opportunity in which to negotiate and file additional Tariff 12 options with inbound components would undermine the effectiveness of our bundling restriction.

We are now in a better position to evaluate the effect that grandfathering options filed during a limited period after August 1 will have on the policies we adopted in the Report and Order. In order for AT&T to have filed these options within thirty days after the adopting of the Report and Order, we believe that the lengthy negotiations typically required to develop such options would have to have been completed or substantially completed by August 1, 1991. Under the circumstances, denying these customers the opportunity to reap the fruits of their negotiations would be unduly harsh and unfair. Additionally, we conclude that a limited extension of the grandfathering date, which would allow only this small number of additional Tariff 12 options to become effective, is consistent with our goal of avoiding customer disruption and will not significantly affect competition in the marketplace or undermine the policy concerns underlying the bundling restrictions.

Ordering clause

1. Accordingly, it is ordered that, pursuant to authority contained in section 4 of the Communications Act of 1934, as amended, 47 U.S.C. 154, and § 1.108 of the Commissions Rules, 47 CFR 1.108, the August 1, 1991 cut-off date of grandfathering provision of the Report and Order is hereby extended, effective immediately upon release of this Memorandum Option and Order, to include Tariff 12 options filed before September 1, 1991.

Federal Communications Commission.

Donna R. Searcy,

Secretary.

[FR Doc. 91-30644 Filed 12-23-91, 8:45 am]

BILLING CODE 5712-01-M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 625

[Docket No. 911194-1294]

Summer Flounder Fishery; Corrections

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Emergency interim rule; corrections.

SUMMARY: This document corrects errors in the emergency interim rule for the Fishery Management Plan for the Summer Flounder Fishery, which was published December 5, 1991 (56 FR 63685).

EFFECTIVE DATE: December 2, 1991.

FOR FURTHER INFORMATION CONTACT: Richard G. Seamans, Jr., Senior Resource Policy Analyst, 508-281-9244, or Phil Williams, NMFS, National Sea Turtle Coordinator, 301-713-2322.

In rule document 91-29179 beginning on page 63685, in the issue of Thursday, December 5, 1991, make the following corrections:

1. The **SUMMARY,** on page 63685, in the third column, on the 27th line from the top of the page, insert the words "off North Carolina" after the words "of the fishery".

2. In the **SUPPLEMENTARY INFORMATION** section, on page 63688, in the third column, on the first line, insert the words "off North Carolina" after the word "waters".

3. In the **SUPPLEMENTARY INFORMATION** section, on page 63688, in the third column, on the tenth line from the bottom of the page, insert the words "the Council and" after the words "consultation with".

4. In the **SUPPLEMENTARY INFORMATION** section, on page 63689, in the first column, on the 28th line from the bottom of the page, insert the words "the Council and" after the word "with"; and on the 12th line from the bottom of the page, insert the words "the Council and" after the words "consult with".

5. In the **SUPPLEMENTARY INFORMATION** section, on page 63689, in the second column, on the seventh line from the top of the page, insert the words "the Council and" after the words "consult with"; and on the 21st line from the top of the page, insert the words "the Council and" after the words "consult with".

§ 625.24 [Corrected]

6. In the regulatory text, on page 63691, in the second column, in § 625.24(b), in the sixth line, insert the following: "or, if the net is not long enough for such a measurement, the terminal ⅓ of the net, measured from the terminus of the codend to the head rope." after the word "net".

§ 625.26 [Corrected]

7. In the regulatory text, on page 63691, in the third column, in § 625.26(c)(1), after the second sentence, insert a new sentence to read: "For purposes of this section, this area is referred to as Federal waters."

§ 625.26 [Corrected]

8. On the same page, in the same column, in § 625.26(c)(2), in the third line, insert the words "the Council and" after the words "after consultation with".

§ 625.26 [Corrected]

9. In the regulatory text, on page 63692, in the first column, in § 625.26(c)(2), in the 14th line from the top of the page, insert the words "of Federal waters" after the word "area".

§ 625.26 [Corrected]

10. On the same page, in the same column, in § 625.26(d), in the fifth line, insert the words "the Council and" before the words "the Director".

§ 625.26 [Corrected]

11. In the regulatory text, on page 63692, in the second column, in § 625.26(e), in the fifth line, insert the words "the Council and" after the words "consultation with";

12. On the same page, in the same column, in § 625.26(f)(1), in the fourth line, insert the words "the Council and" after the words "after consultation with".

William W. Fox, Jr.,

Assistant Administrator for Fisheries, National Marine Fisheries Service.

[FR Doc. 91-30552 Filed 12-19-91; 8:45 am]

BILLING CODE 3510-22-M

50 CFR Part 658

[Docket No. 91930-1305]

RIN 0648-AE34

Shrimp Fishery of the Gulf of Mexico

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Final rule.

SUMMARY: NMFS amends the regulations that implement the Fishery Management Plan for the Shrimp Fishery of the Gulf of Mexico (FMP) to modify, temporarily, the boundary of the Tortugas shrimp sanctuary to reduce the

area closed to trawl fishing. This action enables fishermen to harvest marketable-sized shrimp during specified periods from three small areas that otherwise would be closed.

EFFECTIVE DATES: April 11, 1992, through September 30, 1992.

FOR FURTHER INFORMATION CONTACT: Michael E. Justen, 813–893–3161.

SUPPLEMENTARY INFORMATION: The shrimp fishery managed under the FMP and its implementing regulations at 50 CFR part 658, under the authority of the Magnuson Fishery Conservation and Management Act (Magnuson Act). Under the FMP, the Director, Southeast Region, NMFS (Regional Director), may modify by no more than 10 percent the geographical scope of the Tortugas shrimp sanctuary specified at 50 CFR 658.22, after (1) consultation with the Gulf of Mexico Fishery Management Council (Council), (2) consideration of specified criteria, and (3) determination that benefits may be increased or adverse impacts decreased by the modification.

The Regional Director, after consulting with the Council and considering the criteria for modifying the sanctuary, determined that small portions of the sanctuary that periodically contain harvestable shrimp should be opened for varying lengths of time during the period April 11, 1992, through September 30, 1992. The areas to be opened are less than 10 percent of the geographical scope of the sanctuary. These openings will increase the benefits for fishermen by optimizing the yield of shrimp. This temporary geographic modification is consistent with Objective 1 of the FMP because it provides temporary economic relief to the stressed fishermen while continuing to optimize the yield of shrimp recruited to the fishery.

The full rationale for opening these small portions of the sanctuary and the recent history of previous openings were discussed in the proposed rule (56 FR 50844, October 9, 1991) and are not repeated here. No comments were received on the proposed rule. The proposed rule is adopted as final without change.

Endangered Species Impacts

A consultation conducted in accordance with section 7 of the Endangered Species Act for similar openings of the Torgugas shrimp sanctuary in 1991 concluded that this action would not adversely affect the populations of endangered or threatened species such as sea turtles. That conclusion remains valid.

Classification

The Assistant Administrator for Fisheries, NOAA (Assistant Administrator), determined that this rule is consistent with the national standards and other provisions of the Magnuson Act and other applicable law.

The Council prepared a regulatory impact review (RIR) for this rule. Based on the RIR, the Assistant Administrator determined that the rule is not major under E.O. 12291.

The General Counsel of the Department of Commerce certified to the Small Business Administration that this rule will not have a significant economic impact on a substantial number of small entities because the geographical area affected by this rule is small and, as a result, the number of shrimp trawlers affected in the Gulf-wide fishery is not substantial. As a result, a regulatory flexibility analysis was not prepared.

The Council prepared an environmental assessment (EA) for this rule and, based on the EA, the Assistant Administrator concluded that there will be no significant impact on the human environment as a rule of this rule.

Amendment 1 to the FMP authorizes the Regional Director, under specified conditions and restrictions, to modify the boundaries of the Tortugas shrimp sanctuary, as is being done in this rule. When Amendment 1 was approved, a determination was made with such modifications would be consistent to the maximum extent practicable with the approved coastal zone management program of Florida, the only state affected by this rule. Consequently, a new consistency determination under the Coastal Zone Management Act is not required.

This rule does not contain a collection-of-information requirement subject to the Paperwork Reduction Act.

This rule does not contain policies with federalism implications sufficient to warrant preparation of a federalism assessment under E.O. 12612.

List of Subjects in 50 CFR Part 658

Fisheries, Fishing, Reporting and recordkeeping requirements.

Dated: December 18, 1991.

Samuel W. McKeen,

Acting Assistant Administrator for Fisheries, National Marine Fisheries Service.

For reasons set forth in the preamble, 50 CFR part 658 is amended as follows:

PART 658—SHRIMP FISHERY OF THE GULF OF MEXICO

1. The authority citation for part 658 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

2. In § 658.22, effective from April 11, 1992, through September 30, 1992, the existing text is designated as paragraph (a) and a new paragraph (b) is added to read as follows:

§ 658.22 Tortugas shrimp sanctuary.

* * * * *

(b) The provisions of paragraph (a) of this section notwithstanding:

(1) Effective from April 11, 1992, through September 30, 1992, that part of the Tortugas shrimp sanctuary seaward of a line connecting the following points is open to trawl fishing: from point T at 24°47.8′N. latitude, 82°01.0′W. longitude to point U at 24°43.83′N. latitude, 82°01.0′W. longitude (on the line denoting the seaward limit of Florida's waters); thence along the seaward limit of Florida's waters, as shown on the current edition of NOAA chart 11439, to point V at 24°42.55′N. latitude, 82°15.0′W. longitude; thence north to point W at 24°43.6′N. latitude, 82°15.0′W. longitude (see figure 1).

(2) Effective from April 11, 1992, through July 31, 1992, that part of the Tortugas shrimp sanctuary seaward of a line connecting the following points is open to trawl fishing: from point W to point V, both points as specified in paragraph (b)(1) of this section, to point G, as specified in paragraph (a) of this section (see figure 1).

(3) Effective from May 26, 1992, through July 31, 1992, that part of the Tortugas shrimp sanctuary seaward of a line connecting the following points is open to trawl fishing: from point F, as specified in paragraph (a) of this section to point Q at 24°46.7′N. latitude, 81°52.2′W. longitude (on the line denoting the seaward limit of Florida's waters); thence along the seaward limit of Florida's waters, as shown on the current edition of NOAA chart 11439, to point U and north to point T, both points as specified in paragraph (b)(1) of this section (see figure 1).

[FR Doc. 91–30700 Filed 12–23–91; 8:45 am]

BILLING CODE 3510–22–M

Proposed Rules

Federal Register
Vol. 56, No. 247
Tuesday, December 24, 1991

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Federal Crop Insurance Corporation

7 CFR Chapter IV

[Document No. 0335s]

Sales Closing, Cancellation, Termination for Indebtedness, and Contract Change Dates

AGENCY: Federal Crop Insurance Corporation, USDA.

ACTION: Notice to provide additional time for public comment.

SUMMARY: The Federal Crop Insurance Corporation (FCIC) hereby publishes this notice to advise all interested parties that it is extending the time allowed for public comment and suggestions on the Sales Closing, Cancellation, Termination for Indebtedness, and Contract Change Dates. The intended effect of this notice is to give the public additional time to make responses and comments on FCIC's consideration of changes of the sales closing, cancellation, termination and contract change dates to dates earlier than those presently established by FCIC.

On Wednesday, November 6, 1991, FCIC published an advance notice of proposed rulemaking with request for comments in the **Federal Register** at 56 FR 56605, to solicit public comment regarding FCIC's consideration of changing the sales closing, cancellation, termination and contract change dates to dates earlier than those presently established by the FCIC.

Written comments, data, and opinions on the proposed rule were originally requested by not later than December 6, 1991.

Several commenters, expressing concern that there would not be sufficient time to assemble data and in-depth analysis, asked FCIC to be allowed a slightly longer comment period. FCIC, in response to these requests, has extended this period of public comment until January 21, 1992.

DATES: Written comments, data, and opinions on this proposed rule published at 56 FR 56605 must be submitted not later than January 21, 1992, to be sure of consideration.

ADDRESSES: Written responses should be sent to Peter F. Cole, Secretary, Federal Crop Insurance Corporation, U.S. Department of Agriculture, Washington, DC 20250.

All written comments received pursuant to this notice, and to the proposed rule at 56 FR 56605, will be available for public inspection and copying in the Office of the Manager, Federal Crop Insurance Corporation, U.S. Department of Agriculture, Washington, DC 20250, during regular business hours, Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Peter F. Cole, Secretary, Federal Crop Insurance Corporation, U.S. Department of Agriculture, Washington, DC 20250, telephone (703) 235–1168.

Done in Washington, DC on December 3, 1991.

Jane A. Wittmeyer,

Acting Manager, Federal Crop Insurance Corporation.

[FR Doc. 91–30612 Filed 12–23–91; 8:45 am]

BILLING CODE 3410–08–M

7 CFR Part 401

[Amendment No. 66; Doc. 0036–S]

ASCS Farm Program Payment Yield Option

AGENCY: Federal Crop Insurance Corporation, USDA.

ACTION: Notice to provide additional time for public comment.

SUMMARY: The Federal Crop Insurance Corporation (FCIC) hereby publishes this notice to advise all interested parties that it is extending the time allowed for public comment and suggestions on the ASCS Farm Program Payment Yield Option proposed to be issued for the 1992 crop year. The intended effect of this notice is to give the public additional time to make responses and comments on this proposed rule.

On Friday, November 8, 1991, FCIC published a notice of proposed rulemaking in the **Federal Register** at 56 FR 57296, to add new provisions permitting the amount of insurance for certain crops to be based on the adjusted yield which the Agricultural Stabilization and Conservation Service (ASCS) has established for the farming unit ("ASCS yield"), rather than the recorded and appraised yield ("Appraised yield") as established by FCIC.

Written comments, data, and opinions on the proposed rule were originally requested by not later than December 9, 1991.

Several commenters, expressing concern that there would not be sufficient time to assemble data and in-depth analysis, asked FCIC to be allowed a slightly longer comment period. FCIC, in response to these requests, has extended this period of public comment until January 21, 1992.

DATES: Written comments, data, and opinions on the proposed rule published at 56 FR 57296 must be submitted not later than January 21, 1992, to be sure of consideration.

ADDRESSES: Written responses should be sent to Peter F. Cole, Secretary, Federal Crop Insurance Corporation, U.S. Department of Agriculture, Washington, DC 20250.

All written comments received pursuant to this notice, and to the proposed rule published at 56 FR 57296, will be available for public inspection and copying in the Office of the Manager, Federal Crop Insurance Corporation, U.S. Department of Agriculture, Washington, DC 20250, during regular business hours, Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Peter F. Cole, Secretary, Federal Crop Insurance Corporation, U.S. Department of Agriculture, Washington, DC 20250, telephone (703) 235–1168.

Done in Washington, DC on December 3, 1991.

Jane A. Wittmeyer,

Acting Manager, Federal Crop Insurance Corporation.

[FR Doc. 91–30613 Filed 12–23–91; 8:45 am]

BILLING CODE 3410–08–M

Rural Telephone Bank

7 CFR Part 1610

Rural Electrification Administration

7 CFR Parts 1717 and 1744

Review and Revision of Rural Electrification Administration and Rural Telephone Bank Loan Documents and Lien Accommodation Procedures

AGENCY: Rural Electrification Administration, and Rural Telephone Bank, USDA.

ACTION: Advance notice of proposed rulemaking; extension of comment period.

SUMMARY: The Rural Electrification Administration (REA) and the Rural Telephone Bank (RTB) published an advance notice of proposed rulemaking on Monday, December 2, 1991, (56 FR 61201), indicating their intention to consider possible revisions that may be desirable in the forms and content of REA Telephone, REA Electric and RTB mortgages and related loan documents, including lien accommodation procedures. The notice provided an opportunity for interested parties to forward comments to REA until January 2, 1992. REA and RTB now propose to extend the comment period until March 2 1992.

DATES: Comments must be received by REA or carry a postmark or equivalent by March 2, 1992.

ADDRESSES: Written comments should be addressed to William F. Albrecht, Director, Program Support Staff, U.S. Department of Agriculture, Rural Electrification Administration, room 2234–S, 14th & Independence Avenue, SW., Washington, DC 20250–1500. REA requires a signed original and 3 copies of all comments (7 CFR 1700.30(e)). All comments received will be made available for public inspection at room 2238–S (address as above) during regular business hours (7 CFR 1.27(b)).

FOR FURTHER INFORMATION CONTACT: F. Lamont Heppe, Jr., Deputy Director, Program Support Staff, U.S. Department of Agriculture, Rural Electrification Administration, room 2234–S, at the above address. Telephone: (202) 720–9550.

SUPPLEMENTARY INFORMATION: REA and RTB published an advance notice of proposed rulemaking on Monday, December 2, 1991, (56 FR 61201), indicating their intention to consider possible revisions that may be desirable in the forms and content of REA Telephone, REA Electric and RTB mortgages and related loan documents, including lien accommodation procedures. REA has received several requests to extend the comment period of this notice to allow more time for consideration of the complex issues involved in these documents. It has been determined that an extension of time would be beneficial and the comment period is hereby extended from January 2, 1992, until March 2, 1992.

Authority: 7 U.S.C. 901–950(b); Pub. L. 99–591; Delegation of Authority by the Secretary of Agriculture, 7 CFR 2.23; Delegation of Authority by the Under Secretary for Small Community and Rural Development, 7 CFR 2.72. 7 U.S.C. 901 et seq., 7 U.S.C. 1921 et seq.

Dated: December 13, 1991.

Michael M.F. Liu,

Acting Administrator.

[FR Doc. 91–30630 Filed 12–23–91; 8:45 am]

BILLING CODE 3410–15–M

Farmers Home Administration

7 CFR Part 1942

Rural Business Enterprise Grants

AGENCY: Farmers Home Administration, USDA.

ACTION: Proposed rule.

SUMMARY: The Farmers Home Administration (FmHA) proposes to amend the Agency's policies and procedures governing the administration of Industrial Development Grants. This action is necessary to implement legislation that establishes a program of grants for broadcasting systems and legislation requiring projects not be subject to a dollar limitation. This action is necessary to remove passthrough grants to businesses as eligible under the program, revises the grant selection priorities, and adds training as an eligible use of grant funds when used for technical assistance purposes. This action is necessary to change the name of the program to more accurately reflect the program purpose and make other clarifications to administrative procedures. Additional conforming amendments will be included for other rules contained in 7 CFR at the final rule stage to reflect the change of the name of the program.

DATE: January 23, 1992.

ADDRESSES: Submit written comments in duplicate to the Office of the Chief, Regulations Analysis and Control Branch. Farmers Home Administration, U.S. Department of Agriculture, room 6348, South Agriculture Building, 14th and Independence Avenue SW., Washington, DC 20250–0700.

FOR FURTHER INFORMATION CONTACT: Nancy Spiker, Program Management Branch, Community Facilities Division, FmHA, USDA, room 6304–S, Washington, DC 20250, Telephone: (202) 720–1490.

SUPPLEMENTARY INFORMATION:

Classification

This action has been reviewed under USDA procedures established in Departmental Regulation 1512–1 which implements Executive Order 12291, and has been determined to be nonmajor since the annual effect of the economy is less than $100 million and there will be no increase in costs or prices for consumers, individual industries, organizations, governmental agencies or geographic regions. There will be no significant adverse effects on competition, employment, investment, productivity innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Environmental Impact Statement

This document has been reviewed in accordance with FmHA Instruction 1940–G, "Environmental Program." FmHA has determined that this action does not constitute a major Federal action significantly affecting the quality of the human environment, and in accordance with the National Environmental Policy Act of 1969, Public Law 91–190, an Environmental Impact Statement is not required.

Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act, the Administrator has determined that this action would not have a significant economic impact on a substantial number of small entities because the action will not affect a significant number of small entities as defined by the Regulatory Flexibility Act (5 U.S.C. 601).

Paperwork Reduction Act

The collection of information requirements contained in this rule have been submitted to OMB for review under section 3504(h) of the Paperwork Reduction Act of 1980. Public reporting burden for this collection of information is estimated to vary from 30 minutes to 40 hours per response, with an average of 1.7 hours per response including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of

information, including suggestions for reducing this burden, to Department of Agriculture, Clearance Officer, OIRM, room 404–W, Washington, DC 20250; and to the Office of Management and Budget, Attention: Desk Officer for the Farmers Home Administration, Washington, DC 20503.

Background

FmHA proposes this action to implement a provision of Public Law 101–624, which establishes a program of grants for broadcasting systems and Public Law 102–142, which requires projects not be subject to a dollar limitation. This action also changes the name of the program to more accurately reflect the program purpose and removes passthrough grants to businesses as eligible under the program. The action adds training as an eligible use of grant funds when used for technical assistance purposes, revises the grant selection priorities to allow a more equitable distribution of grant funds, and makes other clarifications to administrative procedures. FmHA will also make additional conforming amendments for other rules contained in 7 CFR at the final rule stage to reflect the change of the name of the program.

Program Affected

This program, Rural Business Enterprise Grants, is listed in the Catalog of Federal Domestic Assistance as Industrial Grants under Number 10.424. The FmHA program and projects which are affected by this instruction are subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with State and local officials. FmHA conducts intergovernmental consultation in the manner delineated in FmHA Instruction 1940–J.

List of Subjects in 7 CFR Part 1942

Business and industry; Grant programs—Housing and community development; Industrial park; Rural areas.

Therefore, as proposed, chapter XVIII, title 7, Code of Federal Regulations is amended as follows:

PART 1942—ASSOCIATIONS

1. The authority citation for part 1942 continues to read as follows:

Authority: 7 U.S.C. 1989; 5 U.S.C. 301; 7 CFR 2.23; 7 CFR 2.70.

Subpart G—Rural Business Enterprise Grants

2. The title of subpart G of part 1942 is revised to read: "Rural Business Enterprise Grants."

3. Section 1942.304 is revised to read as follows:

§ 1942.304 Definitions.

Project. The result of the use of program funds, i.e., a facility whether constructed by the applicant or a third party from a loan with grant funds, technical assistance, startup operating costs or working capital. A revolving fund established in whole or in part with grant funds will also be considered a project for the purpose of intergovernmental and Environmental Review under § 1942.310, paragraphs (b) and (c), as well as the specific uses of the revolving funds.

Regional Commission grants. Grants made from funds made available to FmHA by the Appalachian Regional Commission (ARC) or other Federal Regional Commissions designated under title V of the Public Works and Economic Development Act of 1965.

Rural and Rural Area. Includes all territory of a State, the Commonwealth of Puerto Rico, the Virgin Islands of the United States, Guam, American Samoa, or the Commonwealth of the Mariana Islands, that is not within the outer boundary of any city having a population of fifty thousand or more and its immediately adjacent urbanized and urbanizing areas with a population density of more than one hundred persons per square mile, as determined by the Secretary of Agriculture according to the latest decennial census of the United States.

Rural Business Enterprise (RBE) grants. Grants made to finance and facilitate development of small and emerging private business enterprises in rural areas. Grants are made from FmHA funds under authority of the Consolidated Farm and Rural Development Act, as amended, section 310B (7 U.S.C. 1932).

Small and emerging private business enterprise. Generally any private business which will employ 50 or fewer new employees and has less than $1 million in projected gross revenues and has or will utilize technological innovations and commercialization of new products that can be produced/manufactured in rural areas and new processes that can be used in such production.

Technical Assistance. A function performed for the benefit of a private business enterprise and is a problem solving activity such as market research, product and/or service improvement, feasibility study, etc.

Television demonstration program. Television programming developed to demonstrate the effectiveness of providing information on agriculture and other issues of importance to farmers and other rural residents.

Urbanized Area. An area immediately adjacent to a city having a population of 50,000 or more which, for general social and economic purposes, constitutes a single community and has a boundary contiguous with that of the city. Such community may be incorporated or unincorporated and extend from the contiguous boundary(ies) to recognizable open country, less densely settled areas, or natural boundaries such as forests or water. Minor open spaces such as airports, industrial sites, recreational facilities, or public parks shall be disregarded. Outer boundaries of an incorporated community extend at least to its legal boundaries. Cities which may have a contiguous border with another city but are located across a river from such city and are recognized as a separate community and are not otherwise considered a part of an urbanized or urbanizing area, as defined in this section, are not in a nonrural area.

Urbanizing Area. A community which is not now, or within the foreseeable future not likely to be, clearly separate from an independent of a city of 50,000 or more population and its immediately adjacent urbanized areas. A community is considered "separate from" when it is separated from the city and its immediately adjacent urbanized area by open country, less densely settled areas, or natural barriers such as forests or water. Minor open spaces such as airports, industrial sites, recreational facilities, or public parks shall be disregarded. A community is considered "independent of" when its social and economic structure (e.g., government; educational, health, and recreational facilities; and business, industry tax base, and employment opportunities) is not primarily dependent on the city and its immediately adjacent urbanized area.

§ 1942.305 [Amended]

4. Section 1942.305(a)(1) is amended in the first sentence by changing the word "ID" to read "RBE."

5. Section 1942.305 is amended by adding new paragraph (a)(3) and revising paragraphs (b)(3)(i), (iii), (iv), and (v) to read as follows:

§ 1942.305 Eligibility and priority.

(a) * * *

(3) Grants may be made to statewide private nonprofit public television systems whose coverage is predominantly rural. An eligible applicant must be organized as a private nonprofit public television system,

licensed by the Federal Communications Commission, and operate statewide and within a coverage area that is predominantly rural.

(b) * * *

(3) * * *

(i) *Population.* Proposed project(s) will primarily be located in a community of (1) between 15,000 and 25,000 population—5 points, (2) between 5,000 and 15,000 population—10 points, (3) under 5,000 population—15 points.

* * * * *

(iii) *Experience.* Applicant has evidence of at least 5 years of successful experience in the type of activity proposed in the application for funds under this subpart. Evidence of successful experience may be (1) a description of experience supplied and certified by the applicant, or (2) a letter of support from appropriate local elected officials explaining the applicant's experience. Experience—10 points.

(iv) *Other* (A) Applicant has evidence that small business development will occur by startup or expansion as a result of the activities to be carried out under the grant. Written evidence of commitment by small business must be provided by FmHA—25 points.

(B) Applicant has evidence of substantial commitment of funds from nonfederal sources for proposed project. An authorized representative of the source organization of the nonfederal funds must provide evidence that the funds are available and will be used for the proposed project. More than 50 percent of the project costs from nonfederal sources—15 points, more than 25 percent but less than 50 percent of project costs from nonfederal sources—10 points, between 5 percent and 25 percent of project costs from nonfederal sources—5 points.

(C) For a grant to establish a revolving fund, the applicant provides evidence to FmHA through loan applications or letters from businesses that the loans are needed by small and emerging businesses in the proposed project area—25 points.

(D) The anticipated development, expansion, or furtherance of business enterprises as a result of the proposed project will create and/or save jobs associated with the affected businesses. The number of jobs must be evidenced by a written commitment from the business to be assisted. One job per each $10,000 or less in grant funds expended—10 points. One job per each $25,000 to $10,000 in grant funds expended—5 points.

(E) The proposed grant project is consistent with, and does not duplicate, economic development activities for the project area under an existing community or economic development plan covering the project area. If no local plan is in existence for the project area, an areawide plan may be used. The plan used must be a plan adopted by the appropriate governmental officials/entities as the area's community or economic development plan. Appropriate plan references and copies of appropriate sections of the plan, as well as evidence of plan adoption by appropriate governmental officials should be provided to FmHA. Project is reflected in a plan—5 points.

(F) Grant projects utilizing funds available under this subpart of less than $100,000—25 points, $100,000 to $200,000—15 points, more than $200,000 but not more than $500,000—10 points.

(G) For grants for television demonstration programs, points will be distributed if the grant request contains justification for a need for the information to be provided—25 points.

(v) *Discretionary.* In certain cases when a grant is an initial grant for funding under this Subpart and is not more than $500,000, FmHA may assign up to 50 points in addition to those that may be assigned in paragraphs (b)(3)(i) through (iv) of this section. Use of these points must include a written justification such as geographic distribution of funds, criteria which will result in substantial employment improvement, mitigation of economic distress of a community through the creation or saving of jobs or emergency situations. For grants of less than $100,000—50 points, $100,000 to $200,000—30 points, more than $200,000 but not more than $500,000—20 points.

§ 1942.306 [Amended]

6. Section 1942.306(a) is amended in the introductory text by changing the phrase "and develop" to read "and/or develop."

7. Section 1942.306 is amended by revising paragraphs (a)(3), (a)(4), (a)(7), and (b), and adding (a)(8) to read as follows:

§ 1942.306 Purposes of grants.

(a) Grant funds may be used to finance and/or develop small and emerging private business enterprises in rural areas including, but not limited to, the following:

* * * * *

(3) loans for startup operating cost and working capital.

(4) technical assistance for private business enterprises.

* * * * *

(7) providing financial assistance to third parties through a loan.

(8) training, when necessary, in connection with technical assistance.

(b) Grants, except grants for television demonstration programs, may be made only when there is a reasonable prospect that they will result in development of small and emerging private business enterprises.

* * * * *

8. Section 1942.307 is amended by removing paragraph (b), redesignating paragraph (c) to (b), and adding new paragraphs (a)(4) and (a)(5) to read as follows:

§ 1942.307 Limitations on use of grant funds.

(a) * * *

(4) For programs operated by cable television systems.

(5) To fund a part of a project which is dependent on other funding unless there is a firm commitment of the other funding to ensure completion of the project.

* * * * *

§ 1942.310 [Amended]

9. Section 1942.310(a) is amended in the third sentence by removing the word, "ID."

10. Section 1942.310 is amended by adding two sentences to the end of paragraph (b)(4); and by revising the introductory text of paragraph (c)(1) to read as follows:

§ 1942.310 Other considerations.

* * * * *

(b) * * *

(4) * * * If the preapplication reflects only one specific project which is specifically identified as the third party recipient for financial assistance, FmHA may perform the appropriate environmental assessment in accordance with the requirements of subpart G of part 1940 of this chapter, and forego initiating a Class II assessment with no public notification. However, the applicant must be advised that if the recipient or project changes after the grant is approved, the project to be assisted under the grant will undergo the applicable environmental review and public notification requirements in Subpart G of Part 1940 of this chapter.

* * * * *

(c) * * *

(1) If a proposed grant is for more than $1 million and will increase direct employment by more than 50 employees, the applicant will be requested to provide a written indication to FmHA which will enable FmHA to determine that the proposal will not result in a

project which is calculated to, or likely to, result in:

* * * * *

§ 1942.310 [Amended]

11. Section 1942.310(c)(4) is amended in the first sentence by removing the word, "ID."

12. Section 1942.311 is amended by revising the last sentence in paragraph (a)(1) to read as follows:

§ 1942.311 Application processing.

(a) * * *

(1) * * * The applicant shall use SF 424.1, "Application for Federal Assistance (For Non-Construction)," or SF 424.2, "Application for Federal Assistance (For Construction)," as applicable when requesting financial assistance under this program.

* * * * *

§ 1942.313 [Amended]

13. In § 1942.313, paragraph (a)(2) is amended by changing the word "ID" to "RBE"; and paragraph (a)(4) is amended by removing "/grants" from the end of the sentence.

14. Section 1942.314 is amended by revising the section heading and adding a new paragraph (g) to read as follows:

§ 1942.314 Grants to provide financial assistance to third parties, television demonstration projects, and technical assistance programs.

* * * * *

(g) For technical assistance and television demonstration program projects, the scope of work should include a budget based on the budget contained in the application, modified or revised as appropriate, which includes salaries, fringe benefits, consultant costs, indirect costs, and other appropriate direct costs for the project.

§ 1942.314 [Amended]

15. Section 1942.314(e) is amended by changing the word "ID" to "RBE."

§ 1942.315 [Amended]

16. Section 1942.315(b) is amended by removing "interim financing" from the last sentence.

November 29, 1991.

La Verne Ausman,

Administrator, Farmers Home Administration.

[FR Doc. 91-30871 Filed 12-23-91; 8:45 am]

BILLING CODE 3410-07-M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD1 91-141]

Drawbridge Operation Regulations Charles River, MA

AGENCY: Coast Guard, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: At the request of the Metropolitan District Commission (MDC), the Coast Guard is considering a change to the regulations governing the Craigie Bridge over the Charles River at mile 1.0 between Boston and Cambridge, Massachusetts, by permitting periods when advance notice for an opening is required. Additionally, the Coast Guard is revising the regulations for the Charles River to remove obsolete regulatory provisions, correct inconsistencies, and reflect physical changes that have occurred to the waterway.

DATES: Comments must be received on or before February 7, 1992.

ADDRESSES: Comments should be mailed to Commander (obr), First Coast Guard District, Bldg. 135A, Governors Island, NY 10004-5073. The comments and other materials referenced in this notice will be available for inspection and copying at the above address and room 628 at the John Foster Williams Building, 408 Atlantic Avenue, Boston, Massachusetts. Normal office hours are between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Comments may also be hand-delivered to these addresses.

FOR FURTHER INFORMATION CONTACT: William C. Heming, Bridge Administrator, First Coast Guard District, (212) 668-7170.

SUPPLEMENTARY INFORMATION:

Request for Comments

Interested persons are invited to participate in this rulemaking by submitting written views, comments, data, or arguments. Persons submitting comments should include their names and addresses, identify the bridge, the specific section of this proposal to which each comment applies, and give reasons for concurrence with or any recommended changes in the proposal. Persons desiring acknowledgement that their comments have been received should enclose a stamped self-addressed post card or envelope.

The Commander, First Coast Guard District, will evalaute all communications received and determine a course of final action on this proposal. The proposed regulations may be changed in light of comments received. The Coast Guard plans no public hearing. Persons may request a public hearing by writing to the Commander (obr), First Coast Guard District at either address under ADDRESSES. If the Coast Guard determines that the opportunity for oral presentations will aid this rulemaking, the Coast Guard will hold a public hearing at a time and place announced by a later notice in the **Federal Register.**

Drafting Information

The drafters of this notice are John McDonald, project officer, and Lieutenant Commander John Astley, project attorney.

Background and Purpose

The Metropolitan District Commission (MDC), requested a change to the regulations for the Craigie Bridge, which, presently, opens on signal except during the morning and evening rush hours from 6:15 a.m. thru 9:10 a.m. and from 3:15 p.m. thru 6:30 p.m., respectively, excluding Sundays and legal holdiays. The MDC has requested that in addition to the existing regulations, that commercial and recreational vessels give 24 hours advance notice for bridge openings to the MDC, from December 1 to March 31. This request is being made because of the limited number of openings during the winter months, and to relieve the bridge owner of the burden of having personnel constantly available to open the draw. Additionally, the present drawbridge regulations for the Charles River do not adequately reflect changes that have occurred since various portions of the regulations were instituted.

Paragraph (a)(1), which gives the requirements for sound signals for bridge openings as two prolonged blasts followed by two short blasts is being changed to comply with the sound signals required for an opening as stated in § 117.15, which is one prolonged blast followed by one short blast. This change will eliminate this discrepancy.

Paragraph (a)(3), which refers to the level of the tide at the Charlestown Navy Yard, will be deleted. the relocation and construction of the MDC Charles River Lock and Dam, at mile 0.5, makes the Charles River non-tidal where these bridges are located.

Paragraph (f) which gives the operating hours for the Lechemere Canal Bridge will be deleted because the Lechemere Canal Bridge was replaced with a fixed bridge in 1986.

Paragraph (g) which gives the operating hours for the Broad Canal Bridges and paragraph (h) which states that the draws of the Broad Canal Bridges need not open for the passage of vessels contradict each other, therefore, paragraph (g) will be deleted and paragraph (h) will be retained but will be listed as paragraph (f) in this revised regulation.

Discussion of Proposed Amendments

The Craigie Bridge over the Charles River between Boston and Cambridge, has vertical clearances of 13' above normal pool elevation. The current regulations for the Craigie Bridge are that the bridge shall open on signal; except that, from 6:15 a.m. to 9:10 a.m. and from 3:15 p.m. to 6:30 p.m., excluding Sundays and legal holidays, the draw need not be opened for the passage of vessels. The proposed regulations will retain the provisions for maintaining the bridge in the closed position during peak traffic periods in the morning and evening rush hours. Additionally, the MDC has requested that at least a 24 hour notice be given by commercial and recreational vessels to open the bridge from December 1 to March 31. There have been only a limited number of openings requested during the proposed time period for the past several years.

Paragraph (a)(1), which gives the requirements for sound signals for bridge openings as two prolonged blasts followed by two short blasts is being changed to comply with the sound signals required for an opening as stated in § 117.15, which is one prolonged blast followed by one short blast.

Paragraph (a)(3), which refers to the levels of the tide at the Charlestown Navy Yard, will be deleted because the MDC lock and dam has been relocated downstream of the bridges making the section of the Charles River where the bridges are located to be non-tidal.

The regulations for the Commercial Avenue Bridge across the Lechemere Canal will be deleted because this bridge was replaced by a fixed span highway bridge in 1986.

The Broad Street Bridges were closed by regulation in 1984 by adding paragraph (h), which indicates that the bridge need not open for the passage of vessels; however, paragraph (g) was not deleted and it states the operating hours for the bridge which contradicts paragraph (h). The intended purpose was to allow this bridge to remain in the closed position as stated in paragraph (h). Therefore, paragraph (g) will be deleted. The wording of paragraph (h) will be retained but it will appear as paragraph (f) in the revised regulations.

Regulatory Evaluation

These regulations are considered to be non-major under Executive Order 12291 on Federal Regulation, and nonsignificant under the Department of Transportation regulatory policies and procedures (44 FR 11034; February 26, 1979). The economic impact is expected to be so minimal that a full regulatory evaluation is unnecessary. This opinion is based on the fact that the regulation will not prevent the mariners from transiting the Craigie Bridge but just require advance notice for openings during the winter months.

Small Entities

The Coast Guard expects the economic impact of this proposal to be minimal on all entities since there have been limited openings during the requested period for advance notice for several years. Because it expects the impact of this proposal to be minimal, the Coast Guard certifies under 5 U.S.C. 605(b) that this proposal, if adopted, will not have a significant economic impact on a substantial number of small entities.

Collection of Information

This rule contains no collection of information requirements under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

Federalism

This action has been analyzed under the principles and criteria in Executive Order 12612, and it has been determined that this proposed regulation does not have sufficient federalism implications to warrant preparation of a federal assessment.

Environment

The Coast Guard considered the environmental impact of this rule and concluded that, under section 2.B.2. of Commandant Instruction M16475.1B, this proposal is categorically excluded from further environmental documentation. A Categorical Exclusion Determination is available in the docket for inspection or copying where indicated under **ADDRESS**.

List of Subjects in 33 CFR Part 117

Bridges.

Regulations

In consideration of the foregoing, the Coast Guard proposes to amend part 117 of title 33, Code of Federal Regulations, as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 49 CFR 1.46; 33 CFR 1.05–1(g).

2. Section 117.591 is revised to read as follows:

§ 117.591 Charles River and its tributaries.

(a) The following requirements apply to all bridges across the Charles River and its tributaries:

(1) Public vessels of the United States, state or local vessels used for public safety and vessels in distress shall be passed through the draw of each bridge as soon as possible without delay at any time. The opening signal from these vessels is four or more short blasts or a whistle or horn, or a radio request.

(2) The owners of these bridges shall provide and keep in good legible condition clearance gauges for each draw with figures not less than 12 inches high designed, installed and maintained according to the provisions of paragraph 118.160 of this chapter.

(3) Trains and locomotives shall be controlled so that any delay in opening the draw span shall not exceed ten minutes. However, if a train moving toward the bridge has crossed the home signal for the bridge before the signal requesting opening of the bridge is given, that train may continue across the bridge and must clear the bridge interlocks before stopping.

(4) Except as provided in paragraph (b) through (f) of this section, the draws shall open on signal.

(b) The draw of the Charlestown Bridge, mile 0.4 at Boston, need not be opened for the passage of vessels.

(c) The draw of the Massachusetts Bay Transportation Authority/Amtrak Bridge, mile 0.8, at Boston, shall open on signal; except that from 6:15 a.m. to 9:10 a.m. and 4:15 p.m. to 6:30 p.m., excluding Sundays and legal holidays, the draw need not be opened for the passage of vessels.

(d) The draw of the Massachusetts Bay Transportation Authority (East Cambridge Vaiduct) railroad Bridge, mile 1.0 at Boston, need not be opened for the passage of vessels. However, the operating machinery of the draw shall be maintained in an operable condition.

(e) The draw of the Metropolitan District Commission Bridge, mile 1.0 at Boston, shall operate as follows:

(1) Open on signal; except that, from 6:15 a.m. to 9:10 a.m. and 3:15 p.m. to 6:30 p.m., daily, excluding Sundays and legal holidays, the draw need not open for the passage of vessels.

(2) From December 1 to March 31, the draw shall open on signal after a 24 hour advance notice is given by calling the telephone number posted at the bridge.

(f) The draws of the bridges across Broad Canal, mile 0.0, need not open for the passage of vessels. However, the draws shall be returned to operable condition within one year after notification by the District Commander to do so.

3. Appendix A to part 117 is amended to add the entries for the Charles River under the State of Massachusetts to read as follows:

APPENDIX A TO PART 117.—DRAWBRIDGES EQUIPPED WITH RADIOTELEPHONES

Waterway	Mile	Location	Bridge name and owner	Call sign	Calling working	
					Channel	Channel
* * *	*	*	* * *	*	*	
Massachusetts						
* * *	*	*	* * *	*	*	
Charles River	0.6	Charlestown	Charles River Dam, MDC	WHV 988	16	13
	1.0	Boston	Craigie, MDC	WHV 989	16	13
* * *	*	*	* * *	*	*	

Dated: December 12, 1991.

K.W. Thompson,

Captain, U.S. Coast Guard, Acting Commander, First Coast Guard District.

[FR Doc. 91-30703 Filed 12-23-91; 8:45 am]

BILLING CODE 4910-14-M

33 CFR Part 155

[CGD 91-034/90-068]

RIN 2115-AD61 and 66

Vessel Response Plans and Carriage and Inspection of Discharge-Removal Equipment

AGENCY: Coast Guard, DOT.

ACTION: Notice of meeting of negotiated rulemaking committee on oil spill response plans.

SUMMARY: As required by section 9(a)(2) of the Federal Advisory Committee Act (5 U.S.C. App.), the Coast Guard is providing a contingent notice of the first meeting of the Oil Spill Response Plan Negotiated Rulemaking Committee to negotiate issues relating to oil spill response plans. This meeting is being announced pending a final decision by the Coast Guard on proceeding with negotiated rulemaking.

DATES: The first meeting of the negotiated rulemaking committee will be held from January 8-10, 1992, between 9 a.m. and 4 p.m. EST, unless a notice is published prior to the date cancelling the meeting.

ADDRESSES: The meeting will be held in room 4234 at DOT Headquarters, 400 Seventh Street SW., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: For information concerning the establishment of the negotiated rulemaking committee, contact the convener, Judith Kaleta, Chief Counsel, Research and Special Programs Administration, U.S. Department of Transportation, at (202) 366-4400 between 9 a.m. and 5:30 p.m. EST, Monday through Friday, except federal holidays.

For information concerning the substantive aspects of oil spill response plans and the carriage of removal equipment by tank vessels, contact LCDR Glenn Wiltshire, Project Manager, OPA 90 Staff (G-MS-1), at (202) 267-6740 between 7 a.m. and 3:30 p.m., Monday through Friday, except federal holidays.

SUPPLEMENTARY INFORMATION: The Coast Guard published a notice of intent to form a negotiated rulemaking committee on November 18, 1991 (56 FR 58202), and a notice with supplemental information on November 29, 1991 (56 FR 60949). These notices indicated that the Coast Guard is considering establishment of a negotiated rulemaking committee to assist the Coast Guard in developing portions of the regulations for tank vessel oil spill response plans and carriage of removal equipment required under sections 311(j)(5) and (j)(6)(B) of the Federal Water Pollution Control Act (33 U.S.C. 1321 *et seq.*) (FWPCA), as amended by section 4202 of the Oil Pollution Act of 1990 (Pub. L. 101-380) (OPA 90). The notices also identified interests that would potentially be affected by the rulemaking. The Coast Guard solicited comments to be submitted by December 18, 1991, on the issues raised in the notices and on applications or nominations for required by the Federal Advisory Committee Act, the committee charter was submitted to and approved by the General Services Administration.

Because of the statutory deadlines imposed for issuance of these rules by OPA 90, the Coast Guard anticipates making a decision on the establishment of a negotiated rulemaking committee soon after the close of the comment period. In the event that the Coast Guard decides to establish a negotiated rulemaking committee, the first committee meeting will begin on January 8, 1992 at 9 a.m. EST. Interested persons may call (202) 267-6739 commencing December 30, 1991 for further information. All applicants for membership will also be notified directly. If the Coast Guard does not establish a negotiated rulemaking committee, it will publish a notice to that effect.

The purpose of this meeting is to: (1) Discuss the charter, goals, and missions of the committee; (2) present the issues to be considered by the committee; (3) complete the membership selection process and (4) approve organizational protocols by which the committee will operate. At the first meeting, the Coast Guard will provide a training session for the committee on the negotiation and rulemaking process, and present the relevant provisions of the FWPCA, as amended by OPA 90. Attendance is open to the interested public. Persons wishing to present oral statements at the meeting should so notify the Project Manager no later than the day before the meeting. Any member of the public may present a written statement to the committee at any time. Additional information may be obtained from LCDR Glenn Wiltshire, Project Manager, OPA 90 Staff (G-MS-1), U.S. Coast Guard, Washington, DC 20593-0001, or by calling (202) 267-6740.

Dated: December 19, 1991.

D.H. Whitten,

Captain, U.S. Coast Guard, Acting Chief, Office of Marine Safety, Security and Environmental Protection.

[FR Doc. 91-30841 Filed 12-20-91; 1:26 pm]

BILLING CODE 4910-14-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[OAQPS # CA-12-13-5337; FRL-4086-9]

Approval and Promulgation of Implementation Plans, California State Implementation Plan Revision; Placer County Air Pollution Control District and San Diego County Air Pollution Control District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed rulemaking.

SUMMARY: EPA is proposing a limited approval and limited disapproval of revisions to the California State Implementation Plan (SIP) adopted by the Placer County Air Pollution Control District ("Placer") on September 25, 1990 and the San Diego County Air Pollution Control District ("San Diego") on July 3, 1990. The California Air Resources Board submitted these revisions on April 5, 1991. The revisions concern Placer's Rule 223, Can Coating, which controls the emission of volatile organic compounds (VOCs) from can coating operations, Placer's Rule 410, Recordkeeping for Volatile Organic Compound Emissions, which contains recordkeeping and test method provisions, and San Diego's Rule 67.4, Metal Container, Metal Closure, and Metal Coil Coating Operations, which controls the emission of VOCs from can and coil coating operations. EPA has evaluated the revisions to Placer's Rules 223 and 410 and San Diego's Rule 67.4 and is proposing a limited approval under sections 110(k)(3) and 301(a) of the Clean Air Act Amendments of 1990 (CAAA) because these revisions strengthen the SIP. At the same time, EPA is proposing a limited disapproval of Placer's Rules 223 and 410 and San Diego's Rule 67.4 because the rules do not fully meet the Part D, section 182(a)(2)(A) requirement of the CAAA.

DATES: Comments must be received on or before January 23, 1992.

ADDRESSES: Comments may be mailed to: Esther Hill, Northern California, Nevada and Hawaii Rulemaking Section (A-5-4), Air and Toxics Division, Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105.

Copies of the rule revisions and EPA's evaluation report of each rule are available for public inspection at EPA's Region 9 office during normal business hours. Copies of the submitted rule revisions are also available for inspection at the following locations:

California Air Resources Board, Stationary Source Division, Rule Evaluation Section, 1219 "K" Street, Sacramento, CA 95814.

Placer County Air Pollution Control Agency, 11464 B Avenue, Auburn, CA 95603.

San Diego County Air Pollution Control Agency, 9150 Chesapeake Drive, San Diego, CA 92123-1095.

FOR FURTHER INFORMATION CONTACT: Doris Lo, Northern California, Nevada and Hawaii Rulemaking Section (A-5-4), Air and Toxics Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105, Telephone: (415) 744-1187, FTS: 484-1187.

SUPPLEMENTARY INFORMATION:

Background

On March 3, 1978, EPA promulgated a list of ozone nonattainment areas under the provisions of the Clean Air Act that included the San Diego County Air Pollution Control District ("San Diego"). 43 FR 8964, 40 CFR 81.305. On September 12, 1979, EPA promulgated a list of ozone nonattainment areas under the provisions of the Clean Air Act (CAA or the Act) that included the Placer County Air Pollution Control District ("Placer"). 44 FR 53081, 40 CFR 81.305. Because neither San Diego nor Placer were able to reach attainment by the statutory attainment date of December 31, 1982, California requested, and EPA approved, an extension of the attainment date to December 31, 1987. CAA Section 172(a)(2). Neither Placer nor San Diego attained the ozone standard by the approved attainment date. On May 26, 1988, EPA notified the Governor of California that Placer's and San Diego's portions of the California State Implementation Plan (SIP) were inadequate to attain and maintain the ozone standard and requested that deficiencies in the existing SIP be corrected (EPA's SIP-Call). On November 15, 1990, the Clean Air Act Amendments of 1990 (CAAA) were enacted. Public Law 101-549, 104 Stat. 1399, codified at 42 U.S.C. §§ 7401-7671q. In section 182(a)(2)(A) of the CAAA, Congress statutorily adopted the requirement that nonattainment areas fix their deficient reasonably available control technology (RACT) rules for ozone and established a deadline of May 15, 1991 for states to submit corrections of those deficiencies.

Section 182(a)(2)(A) applies to areas classified as marginal or above and requires such areas to adopt and correct RACT rules pursuant to pre-amended section 172(b) as interpreted in pre-amendment guidance.[1] EPA's SIP-Call used that guidance to indicate the necessary corrections for specific nonattainment areas. Placer is classified as serious and San Diego is classified as severe [2]; therefore, these two areas are subject to the RACT fix-up requirement and the May 15, 1991 deadline.

The State of California submitted many revised RACT rules to EPA for incorporation into its SIP on April 5, 1991, including the rules being acted on in this notice. This notice addresses EPA's proposed action for Placer's Rule 223, Can Coating, Placer's Rule 410, Recordkeeping for Volatile Organic Compound Emissions, and San Diego's Rule 67.4, Metal Container, Metal Closure, and Metal Coil Coating Operations. These submitted rules were found to be complete on May 21, 1991 pursuant to EPA's completeness criteria set forth in 40 CFR part 51 appendix V [3] and are being proposed for limited approval and limited disapproval.

Rule 223 controls the emission of volatile organic compounds (VOCs) from can coating operations, Rule 410 contains recordkeeping requirements and test method requirements which are referenced by Placer's volatile organic compound (VOC) rules, and Rule 67.4 controls the emission of VOCs from can and coil coating operations. VOCs contribute to the production of ground level ozone and smog. Rules 223 and 67.4 were originally adopted as part of Placer's and San Diego's effort to achieve the National Ambient Air Quality Standard (NAAQS) for ozone and have been revised in response to EPA's SIP-Call and the section 182(a)(2)(A) CAAA requirement. Rule 410 is a new rule which has been adopted to meet EPA's SIP-Call and the section 182(a)(2)(A) CAAA requirement. The following is EPA's evaluation and proposed action for Placer's Rules 223 and 410 and San Diego's Rule 67.4.

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[1] Among other things, the pre-amendment guidance consists of those portions of the proposed Post-1987 ozone and carbon monoxide policy that concern RACT, 52 FR 45044 (November 24, 1987); "Issues Relating to VOC Regulation Cutpoints, Deficiencies, and Deviations, Clarification to appendix D of November 24, 1987 Federal Register Notice" (Blue Book) (notice of availability was published in the Federal Register on May 25, 1988); and the existing control technique guidelines (CTGs).

[2] Placer and San Diego were redesignated nonattainment and classified by operation of law pursuant to sections 107(d) and 181(a) upon the date of enactment of the CAAA. See 56 FR 56694 (November 6, 1991).

[3] EPA has since adopted completeness criteria pursuant to section 110(k)(1)(A) of the amended Act. See 56 FR 42216 (August 26, 1991).

EPA Evaluation and Proposed Action

In determining the approvability of a VOC rule, EPA must evaluate the rule for consistency with the requirements of the CAAA, EPA regulations and EPA policy. These requirements are found in section 110 and Part D of the CAAA and in 40 CFR part 51 (Requirements for Preparation, Adoption, and Submittal of Implementation Plans), and guidance referred to in footnote 1. Among those provisions is the requirement that a VOC rule must, at a minimum, provide for the implementation of reasonably available control technology (RACT) for stationary sources of VOC emissions. This requirement was carried forth from the preamended Act.

For the purpose of assisting state and local agencies in developing RACT rules, EPA prepared a series of Control Technique Guideline (CTG) documents which specify the minimum requirements that a rule must contain in order to be approved into the SIP. Under the amended Act, Congress ratified EPA's use of these documents, as well as other Agency policy, for requiring States to "fix-up" their RACT rules. See section 182(a)(2)(A). The CTG applicable to Rule 223 and to Rule 67.4 is entitled, "Surface Coating (Volume II—Surface Coating of Cans, Coils, Paper, Fabrics, Automobiles, and Light-Duty Trucks)", EPA document # EPA–450/2–77–008. Further interpretations of EPA policy are found in the Blue Book. In general, these guidance documents have been set forth to ensure that VOC rules are fully enforceable and strengthen or maintain the SIP.

Placer's submitted Rule 223, Can Coating, includes the following revisions from the current SIP rule:

—Specification of test methods for determining the VOC, water and exempt solvent content of coatings;
—Specification of recordkeeping requirements by referencing Rule 410, Recordkeeping for VOC Emissions (see below);
—Deletion of provisions which allow for alternative emission control plans;
—Addition of new coating categories and more stringent VOC limits;
—Revision of the VOC definition to include compounds which have been exempted by EPA as negligibly reactive;
—Deletion of past compliance dates;
—Addition of new definitions;
—Language modifications and rule reorganization for clarity.

Placer's Rule 410, Recordkeeping for Volatile Organic Compound Emissions is a new rule which was adopted to address the lack of recordkeeping provisions that are found in Placer's SIP-approved VOC rules, such as Rule 223. Rule 410 also contains some definitions and test methods for compliance determinations.

San Diego's submitted Rule 67.4, Metal Container, Metal Closure, and Metal Coil Coating Operations, includes the following revisions from the current SIP rule:

—Specification of test methods for determining the VOC, water and exempt solvent content of coatings;
—Addition of add-on control requirements;
—Specification of recordkeeping requirements;
—Deletion of provisions which allow for alternative emission control plans;
—Addition of new coating categories and more stringent VOC limits;
—Revision of the VOC definition to include compounds which have been exempted by EPA as negligibly reactive;
—Deletion of past compliance dates;
—Addition of new definitions;
—Revision of the Rule title.

EPA has evaluated Placer's submitted Rules 223 and 410 and San Diego's submitted Rule 67.4 for consistency with the CAAA, EPA regulations and EPA policy and has found that the revisions address and correct many deficiencies previously identified by EPA. These corrected deficiencies have resulted in clearer, more enforceable rules. Furthermore, the addition of more stringent coating limits in submitted Rules 223 and 67.4 should lead to more emission reductions.

Although the approval of Placer's Rules 223 and 410, and San Diego's Rule 67.4, will strengthen the SIP, these rules still contain deficiencies which were required to be corrected pursuant to the section 182(a)(2)(A) requirement of Part D of the CAAA. For Placer's submitted Rule 223, the remaining deficiencies involve the allowance of non-specified test methods and the approvaility of Rule 410 and its recordkeeping requirements. For Placer's submitted Rule 410, the remaining deficiencies involve the allowance of non-specified test methods. For San Diego's Rule 67.4, the remaining deficiencies involve the allowance of non-specified test methods and an incorrectly specified capture efficiency test method. Because of these deficiencies, the rules are not approvable pursuant to the section 182(a)(2)(A) requirement of part D of the CAAA because they are not conistent with the interpretation of the section 172 requirement as found in the aforementioned Blue Book and may lead to enforceability problems.

Because of the above deficiencies, EPA cannot grant full approval of these rules under section 110(k)(3) and Part D. Also, because the submitted rules are not composed of separable parts which meet all the applicable requirements of the CAAA, EPA cannot grant partial approval of the rules under section 110(k)(3). However, EPA may grant a limited approval of the submitted rules under section 110(k)(3) in light of EPA's authority pursuant to section 301(a) to adopt regulations necessary to further air quality by strengthening the SIP. The approval is limited in the sense that the rules are not being fully approved under 110(k)(3) and part D of the CAAA since they do not meet the section 182(a)(2)(A) requirement. Thus, in order to strengthen the SIP, EPA is proposing a limited approval of Placer's submitted Rules 223 and 410 and San Diego's submitted Rule 67.4 under section 110(k)(3) and 301(a) of the CAAA.

At this same time, EPA is also proposing a limited disapproval of these rules because they contain deficiencies that have not been corrected as required by section 182(a)(2)(A) of the CAAA, and, as such, the rules do not fully meet the requirements of Part D of the Act. Under section 179(a)(2), if the Administrator disapproves a submission under section 110(k) for an area designated nonattainment, based on the submission's failure to meet one or more of the elements required by the Act, the Administrator must apply one of the sanctions set forth in section 179(b) unless the deficiency has been corrected within 18 months of such disapproval. Section 179(b) provides two sanctions available to the Administrator: Highway funding and offsets. The 18 month period referred to in section 179(a) will begin at the time EPA publishes final notice of this disapproval. Moreover, the final disapproval triggers the federal implementation plan (FIP) requirement under section 110(c).

Nothing in this action should be construed as permitting or allowing or establishing a precedent for any future request for revision to any state implementation plan. Each request for revision to the state implementation plan shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

Regulatory Process

Under 5 U.S.C. section 605(b), I certify that this SIP revision will not have a significant economic impact on a substantial number of small entities. (See 46 FR 8709.)

This action has been classified as a table 2 action by the Regional Administrator under the procedures published in the **Federal Register** on January 19, 1989 (54 FR 2214–2225). EPA has submitted a request for a permanent waiver for Table 2 and Table 3 SIP revisions. OMB has agreed to continue the temporary waiver until such time as it rules on EPA's request.

List of Subjects in 40 CFR Part 52

Air pollution control, Ozone, Hydrocarbons, Reporting and recordkeeping requirements.

Authority: 42 U.S.C. 7401–7642.

Dated: December 12, 1991.

John Wise,

Acting Regional Administrator.

[FR Doc. 91–30692 Filed 12–23–91; 8:45 am]

BILLING CODE 6560–50–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Part 3800

RIN 1004–AB 99

[WO–680–4130–02 24 1A]

Surface Management Regulations; Extension of Comment Period

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of extension of comment period.

SUMMARY: The notice of intent to propose rulemaking that would amend subpart 3809 of 43 CFR part 3800 was published in the **Federal Register** on October 23, 1991 (56 FR 54815), with the comment period ending January 3, 1992. The comment period is being extended to January 15, 1992, in response to public requests.

DATES: The period for submission of comments is hereby extended to January 15, 1992. Comments received or postmarked after this date may not be considered in developing the proposed rule.

ADDRESSES: Comments should be sent to: Director (140), Bureau of Land Management, room 5555, Main Interior Building, 1849 C Street, NW., Washington, DC 20240. Comments will be available for public review in room 5555 of the above address during regular business hours (7:45 a.m. to 4:15 p.m.), Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Bob Anderson, (916) 978–4735.

Dated: December 18, 1991.

Richard Roldan,

Deputy Assistant Secretary of the Interior.

[FR Doc. 91–30656 Filed 12–23–91; 8:45 am]

BILLING CODE 4310–84–M

Fish and Wildlife Service

50 CFR Part 17

RIN 1018–AB52

Endangered and Threatened Wildlife and Plants: Notice of Reopening of Comment Period During the 6-Month Extension on the Proposed Rule for Eutrema Penlandii (Penland Alpine Fen Mustard)

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; Notice of reopening of comment period during the 6-month extension.

SUMMARY: Because of requests by a number of private individuals, the U.S. Fish and Wildlife Service (Service) gives notice of reopening the comment period on the proposed determination of threatened status for the plant species *Eutrema penlandii* (Penland alpine fen mustard). This species is endemic to the Mosquito Range in the central Rocky Mountains of Colorado. Reopening the comment period will allow comments on this proposal from all interested parties.

DATES: Comments will now be received until February 7, 1992.

ADDRESSES: Written comments and materials should be sent to the State Supervisor, U.S. Fish and Wildlife Service, Fish and Wildlife Enhancement, 730 Simms Street, room 290, Golden, Colorado 80401. Comments and materials and the complete file for this notice will be available for public inspection, by appointment, during normal business hours at the above address or at the Western Colorado Suboffice, 529–25 1/2 Road, suite B–113, Grand Junction, Colorado 81505–6199.

FOR FURTHER INFORMATION CONTACT: Lee Carlson, State Supervisor, at the Golden address (303–231–5280 or FTS 554–5280).

SUPPLEMENTARY INFORMATION:

Background

Eutrema penlandii (Penland alpine fen mustard) is endemic to the Mosquito Range in the central Rocky Mountains of Colorado. Prior to this past summer, there were eight known occurrences over a 40-kilometer (25 miles) length. *Eutrema penlandii* was proposed for listing as a threatened species on October 15, 1990 (55 FR 41725). A 6-month extension of time for the listing was published on October 28, 1991 (56 FR 55487), bringing the listing deadline to April 15, 1992. A 30-day comment period was granted from October 28, 1991, to November 27, 1991.

Alma London Joint Venture, a mining company, disagreed with the Service's depiction of habitat requirements for *Eutrema penlandii*. They conducted an independent study of the distribution and abundance of the plant species during the summer of 1991. Further, Colorado College of Colorado Springs conducted a study of pH requirements of *Eutrema penlandii* during the summer of 1991. Both groups prepared reports which were submitted to the Service to be used in the decision concerning final listing.

There were numerous requests to extend the comment period and allow interested parties to review and comment on the work conducted by Alma London Joint Venture and Colorado College. it is because of these requests that the Service is extending the comment period for 45 days. Anyone who wishes to review and comment on the reports should contact Lee Carlson, State Supervisor (see "**ADDRESSES**" section).

Upon review of the reports and all pertinent comments received, the Service will decide either to continue with the final listing of the species or to withdraw the proposal for *Eutrema penlandii* as provided under Section 4(b)(6)(B)(i) of the Endangered Species Act.

Author

The primary author of this notice is Lee Carlson (see "**ADDRESSES**" above).

Authority

The authority for this section is the Endangered Species Act of 1973 (16 U.S.C. et seq.).

List of Subjects in 50 CFR Part 17

Endangered and threatened species. Exports, Imports, Reporting and recordkeeping requirements, and Transportation.

Dated: December 16, 1991.

Galen L. Buterbaugh,

Regional Director, Fish and Wildlife Service

[FR Doc. 91–30636 Filed 12–23–91; 8:45 am]

BILLING CODE 4310–55–M

Notices

Federal Register
Vol. 56, No. 247
Tuesday, December 24, 1991

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[TR-92-01]

Federal State Marketing Improvement Program; Program Continuation

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice inviting applications for Fiscal Year 1992 Grant Funds under the Federal-State Marketing Improvement Program (FSMIP).

SUMMARY: Notice is hereby given that the Federal-State Marketing Improvement Program was allocated $1,250,000 in the Federal Budget for Fiscal Year 1992. Funds remain available for this program. States interested in obtaining funds under the program are invited to submit proposals for marketing studies. Only State Departments of Agriculture or State Agencies are eligible for these funds.

DATES: Applications will be accepted until September 1992.

ADDRESSES: Proposals may be sent to Dr. Harold S. Ricker, Assistant Director, Federal-State Marketing Improvement Program, Transportation and Marketing Division, AMS, USDA, room 4006-South Building, P.O. Box 96456, Washington, DC 20090–6456.

FOR FURTHER INFORMATION CONTACT: Dr. Harold S. Ricker, (202) 720–2704.

SUPPLEMENTARY INFORMATION: The Federal-State Marketing Improvement Program is authorized under section 204(b) of the Agricultural Marketing Act of 1946 (7 U.S.C. 1621 *et seq.*). The program is a matching fund program designed to assist State Departments of Agriculture or State Agencies in conducting feasibility studies related to the marketing or agricultural products. Organizations interested in conducting a marketing study should contact their State Department of Agriculture Marketing Division to discuss their proposal. Mutually accepted proposals must be submitted through the State Office and be accompanied by a completed Standard Form 424 and a detailed budget statement. FSMIP funds may not be used for advertising or the purchase of equipment and facilities. Guidelines may be obtained from your State Department of Agriculture or the above AMS contact.

In terms of objectives, the States are encouraged to submit proposals regarding: (1) Studies to identify new crops, markets, and marketing systems for agricultural products, both domestically and internationally; (2) studies to improve efficiency of the marketing system to enhance competitiveness and profitability; and, (3) studies to help maintain product quality through new handling, processing, and distribution techniques. Proposals addressing other marketing objectives will also receive consideration.

The Federal-State Marketing Improvement Program is listed in the "Catalog of Federal Domestic Assistance" under No. 10.156 and subject agencies must adhere to title VI of the Civil Rights Act of 1964 which bars discrimination in all Federally assisted programs.

Done at Washington, DC this day of December 19, 1991.

Kenneth C. Clayton,

Acting Administrator.

[FR Doc. 91–30670 Filed 12–23–91; 8:45 am]

BILLING CODE 3410-02-M

Animal and Plant Health Inspection Service

[Docket No. 91-173]

National Boll Weevil Cooperative Control Program; Availability of Final Environmental Impact Statement

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: This notice advises the public that the Animal and Plant Health Inspection Service has prepared and is making available a final environmental impact statement (FEIS) for the National Boll Weevil Cooperative Control Program. We sent the FEIS to the Environmental Protection Agency on December 18, 1991.

ADDRESSES: Requests for copies of the FEIS should be addressed to: Nancy Sweeney, Project Leader, Environmental Analysis and Documentation, Biotechnology, Biologics, and Environmental Protection, APHIS, USDA, room 828, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782.

Copies of the FEIS also may be obtained at any of the following locations:

1. Southeastern Regional Office: A.S. Elder, Regional Director, 3505 25th Avenue, Building 1 North, Gulfport, MS 39501, (601) 863–1813.

2. South Central Regional Office: Robert L. Williamson, Regional Director, 3505 Boca Chica Boulevard, suite 360, Brownsville, TX 78521–4065, (512) 548–2750/51/52/53.

3. Western Regional Office: James Reynolds, Regional Director, 9580 Micron Avenue, suite 1, Sacramento, CA 95827, (916) 551–3220.

A copy of the FEIS may be reviewed at the APHIS Reading Room, USDA (reference copy only): Room 1141, South Building, 14th Street and Independence Avenue, SW., Washington, DC 20250, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays.

FOR FURTHER INFORMATION CONTACT: William Grefenstette, Operations Officer, Operational Support, Planning and Design, Plant Protection and Quarantine, APHIS, USDA, room 816, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, (301) 436–6716.

SUPPLEMENTARY INFORMATION:

Background

On August 1, 1989, we published in the **Federal Register** (54 FR 31710–31711, Docket No. 89–134), a notice announcing the availability of a draft environmental impact statement (EIS) for the National Boll Weevil Cooperative Control Program. The notice also requested comments on or before October 2, 1989. On October 12, 1989, we published in the **Federal Register** (54 FR 41859–41860, Docket No. 89–168), a notice extending the comment period on the draft EIS to November 3, 1989. In response to some of the comments received, we published a notice in the **Federal Register** on August 2, 1991, (56 FR 37073, Docket No. 91–111) announcing the availability of a supplement to the EIS to further address the impacts the program may have in Alabama and on endangered and

threatened species across the Cotton Belt. The notice also requested comments on the supplement on or before September 16, 1991.

The final environmental impact statement (FEIS) considers and responds to all comments received on the draft EIS and its supplement that were received on or before the stated deadlines.

Pursuant to § 1506.9 of the regulations of the Council on Environmental Quality (40 CFR 1506.9), we transmitted the FEIS to the Environmental Protection Agency on December 18, 1991.

Done in Washington, DC, this 19th day of December 1991.

Robert Melland,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 91-30664 Filed 12-23-91; 8:45 am]

BILLING CODE 3410-34-M

[Docket 91-169]

Availability of Environmental Assessments and Findings of No Significant Impact Relative to Issuance of Permits to Field Test Genetically Engineered Organisms

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that two environmental assessments and findings of no significant impact have been prepared by the Animal and Plant Health Inspection Service relative to the issuance of permits to allow the field tsting of genetically engineered organisms. The assessments provide a basis for the conclusion that the field testing of these genetically engineered organisms will not present a risk of the introduction or dissemination of a plant pest and will not have a significant impact on the quality of the human environment. Based on the findings of no significant impact, the Animal and Plant Health Inspection Service has determined that environmental impact statements need not be prepared.

ADDRESSES: Copies of the environmental assessments and findings of no significant impact are available for public inspection at USDA, room 1141, South Building, 14th Street and Independence Avenue, SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays.

FOR FURTHER INFORMATION CONTACT: Ms. Mary Petrie, Program Specialist, Biotechnology Permits, Biotechnology, Biologics, and Environmental Protection, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, room 850, Federal Building, 6505 Belcrest Road, Hyattsville, MD, 20782 (301) 436-7612. For copies of the environmental assessments and findings of no significant impact, write Mr. Clayton Givens at this same address. The documents should be requested under the permit number listed below.

SUPPLEMENTARY INFORMATION: The regulations in 7 CFR part 340 regulate the introduction (importation, interstate movement, and release into the environment) of genetically engineered organisms and products that are plant pests or that there is reason to believe are plant pests (regulated articles). A permit must be obtained before a regulated article can be introduced into the United States. The regulations set forth procedures for obtaining a limited permit for the importation or interstate movement of a regulated article and for obtaining a permit for the release into the environment of a regulated article. The Animal and Plant Health Inspection Service (APHIS) has stated that it would prepare an environmental assessment and, when necessary, an environmental impact statement before issuing a permit for the release into the environment of a regulated article (see 52 FR 22906).

In the course of reviewing the permit applications, APHIS assessed the impact on the environment of releasing the organisms under the conditions described in the permit applications. APHIS concluded that the issuance of the permits listed below will not present a risk of plant pest introduction or dissemination and will not have a significant impact on the quality of the human environment.

The environmental assessments and findings of no significant impact, which are based on data submitted by the applicants as well as a review of other relevant literature, provide the public with documentation of APHIS' review and analysis of the environmental impacts associated with conducting the field tests.

Environmental assessments and findings of no significant impact have been prepared by APHIS relative to the issuance of the following permits to allow the field testing of genetically engineered organisms:

Permit No.	Permittee	Date issued	Organisms	Field test location
91-218-03	University of California, Davis	11-04-91	Apple plants genetically engineered to express an insecticidal crystal protein of *Bacillus thuringiensis* subsp. *kurstaki* HD-73.	Stanislaus County, California.
91-205-02	Petoseed Research Center	11-19-91	Tomato plants genetically engineered to express polygalacturonase (PG), pectiesterase (PE), and ethylene forming enzyme as antisense genes.	Hendry County, Florida.

The environmental assessments and findings of no significant impact have been prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4331 *et seq.*), (2) Regulations of the Council on Environmental Quality for Implementing the Procedural Provisions of NEPA (40 CFR parts 1500-1509), (3) USDA Regulations Implementing NEPA (7 CFR part 1b), and (4) APHIS Guidelines Implementing NEPA (44 FR 50381-50384, August 28, 1979, and 44 FR 51272-51274, August 31, 1979).

Done in Washington, DC, this 19th day of December 1991.

Robert Melland,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 91-30668 Filed 12-23-91; 8:45 am]

BILLING CODE 3410-34-M

[Docket No. 91-181]

Receipt of Permit Applications for Release Into the Environment of Genetically Engineered Organisms

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that three applications for permits to release genetically engineered organisms into the environment are

being reviewed by the Animal and Plant Health Inspection Service. The applications have been submitted in accordance with 7 CFR part 340, which regulates the introduction of certain genetically engineered organisms and products.

ADDRESSES: Copies of the applications referenced in this notice, with any confidential business information deleted, are available for public inspection in room 1141, South Building, United States Department of Agriculture, 14th Street and Independence Avenue, SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. You may obtain a copy of this document by writing to the person listed under **FOR FURTHER INFORMATION CONTACT.**

FOR FURTHER INFORMATION CONTACT: Mary Petrie, Program Specialist, Biotechnology, Biologics, and Environmental Protection, Biotechnology Permits, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, room 850, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, (301) 436–7612.

SUPPLEMENTARY INFORMATION: The regulations in 7 CFR part 340, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason To Believe Are Plant Pests," require a person to obtain a permit before introducing (importing, moving interstate, or releasing into the environment) into the United States certain genetically engineered organisms and products that are considered "regulated articles." The regulations set forth procedures for obtaining a permit for the release into the environment of a regulated article, and for obtaining a limited permit for the importation or interstate movement of a regulated article.

Pursuant to these regulations, the Animal and Plant Health Inspection Service has received and is reviewing the following applications for permits to release genetically engineered organisms into the environment:

Application No.	Applicant	Date received	Organism	Field test location
91-322-01	North Carolina State University	11-18-91	Tobacco plants genetically engineered to express a coat protein of a highly aphid-transmissible strain of tobacco etch virus (TEV).	Wake County, North Carolina.
91-324-01	Frito-Lay, Incorporated	11-20-91	Potato plants genetically engineered to express a *Bacillus thuringiensis* subsp. *tenebrionis* (Btt) gene, for tolerance to the Colorado potato beetle.	Oneida County, Wisconsin.
91-324-03	Frito-Lay, Incorporated	11-20-91	Potato plants genetically engineered to express a chitinase gene, for resistance to *Rhizoctonia solani.*	Oneida County, Wisconsin.

Done in Washington, DC, this 19th day of December 1991.

Robert Melland,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 91-30665 Filed 12-23-91; 8:45 am]

BILLING CODE 3410-34-M

[Docket No. 91-175]

Availability of List of U.S. Veterinary Biological Product and Establishment Licenses, and U.S. Veterinary Biological Product Permits, Issued, Suspended, Revoked, or Terminated

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: This notice is to advise the public of veterinary biological product and establishment licenses and veterinary biological product permits that were issued, suspended, revoked, or terminated by the Animal and Plant Health Inspection Service, during the months of October and November 1991. These actions have been taken in accordance with the regulations issued pursuant to the Virus-Serum-Toxin Act. The purpose of this notice is to notify interested persons of the availability of a list of these actions and advise interested persons that they may request to be placed on a mailing list to receive the listing.

FOR FURTHER INFORMATION CONTACT: Joan Montgomery, Program Assistant, Veterinary Biologics, Biotechnology, Biologics, and Environmental Protection, APHIS, USDA, room 838, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, (301) 436–4873. For copies of the list or to be placed on the mailing list, write to Ms. Montgomery at the above address.

SUPPLEMENTARY INFORMATION: The regulations in 9 CFR part 102, "Licenses For Biological Products," require that every person who prepares certain biological products that are subject to the Virus-Serum-Toxin Act (21 U.S.C. 151 *et seq.*) shall hold an unexpired, unsuspended, and unrevoked U.S. Veterinary Biological Product License. The regulations set forth the procedures for applying for a license, the criteria for determining whether a license shall be issued, and the form of the license.

The regulations in 9 CFR part 102 also require that each person who prepares biological products that are subject to the Virus-Serum-Toxin Act (21 U.S.C. 151 *et seq.*) shall hold a U.S. Veterinary Biologics Establishment License. The regulations set forth the procedures for applying for a license, the criteria for determining whether a license shall be issued, and the form of the license.

The regulations in 9 CFR part 104, "Permits for Biological Products," require that each person importing biological products shall hold an unexpired, unsuspended, and unrevoked U.S. Veterinary Biological Product Permit. The regulations set forth the procedures for applying for a permit, the criteria for determining whether a permit shall be issued, and the form of the permit.

The regulations in 9 CFR parts 102 and 105 also contain provisions concerning the suspension, revocation, and termination of U.S. Veterinary Biological Product Licenses, U.S. Veterinary Biologics Establishment and U.S. Veterinary Biological Product Permits.

Each month the Veterinary Biologics section of Biotechnology, Biologics, and Environmental Protection prepares a list of licenses and permits that have been issued, suspended, revoked, or terminated. This notice announces the availability of the lists for October and November 1991. The monthly lists are also mailed on a regular basis to interested persons. To be placed on the mailing list you may call or write the person designated under **FOR FURTHER INFORMATION CONTACT.**

Done in Washington, DC, this 19th day of December 1991.

Robert Melland,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 91-30667 Filed 12-23-91; 8:45 am]

BILLING CODE 3410-34-M

Federal Crop Insurance Corporation

[Document No. 0331s]

Request for Comments on Methodology for Yield Determinations

AGENCY: Federal Crop Insurance Corporation, USDA.

ACTION: Notice to provide additional time for public comment.

SUMMARY: The Federal Crop Insurance Corporation (FCIC) hereby publishes this notice to advise all interested parties that it is extending the time allowed for public comment and suggestions on the Request for Comments on Methodology for Yield Determinations. The intended effect of this notice is to give the public additional time to make responses and comments on the FCIC methodology for Yield Determinations.

On Friday, November 8, 1991, FCIC published a notice with request for comments in the **Federal Register** at 56 FR 573111, to solicit public comment, suggestions, and analytical studies concerning procedures to determine average yields for crop insurance purposes.

Written comments, data, and opinions on this notice were originally requested by not later than December 8, 1991.

Several commenters, expressing concern that there would not be sufficient time to assemble data and in-depth analysis, asked FCIC to be allowed a slightly longer comment period. FCIC, in response to these requests, has extended this period for public comment until January 21, 1992.

DATES: Written comments, data, and opinions on the proposed rule published at 56 FR 57311 must be submitted not later than January 21, 1992, to be sure of consideration.

ADDRESSES: Written responses should be sent to Peter F. Cole, Secretary, Federal Crop Insurance Corporation, U.S. Department of Agriculture, Washington, DC 20250.

All written comments received pursuant to this notice, and to the request for comments on the methodology for yield determinations at 56 FR 57311, will be available for public inspection and copying in the Office of the Manager, Federal Crop Insurance Corporation, U.S. Department of Agriculture, Washington, DC 20250, during regular business hours, Monday through Friday.

Done in Washington, DC on December 3, 1992.

Jane A. Wittmeyer,

Acting Manager, Federal Crop Insurance Corporation.

[FR Doc. 91-30614 Filed 12-23-91; 8:45 am]

BILLING CODE 3410-08-M

Packers and Stockyards Administration

Deposting of Stockyards

Notice is hereby given that the livestock markets named herein, originally posted on the dates specified below as being subject to the Packers and Stockyards Act, 1921, as amended (7 U.S.C. 181 *et seq.*), no longer come within the definition of a stockyard under the Act and are therefore no longer subject to the provisions of the Act.

	Facility No., name, and location of stockyard	Date of posting
AL-180	Marion Stockyard, Marion, AL.	Apr. 9, 1990.
GA-208	Hugh Watson Stockyard, Gainesville, GA.	Jan. 29, 1991.
GA-178	R&T Livestock Company, Millen, GA.	Feb. 17, 1975.
TN-165	Jonesborough Livestock Market, Inc., Telford, TN.	Jan. 7, 1970.
WA-111	Lynden Auction Market, Inc., Lynden, WA.	Jan. 18, 1960.

This notice is in the nature of a change relieving a restriction and, thus, may be made effective in less than 30 days after publication in the **Federal Register** without prior notice or other public procedure. This notice is given pursuant to section 302 of the Packers and Stockyards Act (7 U.S.C. 202) and is effective upon publication in the **Federal Register**.

Done at Washington, DC this 17th day of December, 1991.

Harold W. Davis,

Director, Livestock Marketing Division.

[FR Doc. 91-30663 Filed 12-23-91; 8:45 am]

BILLING CODE 3410-KD-M

Soil Conservation Service

Muddy Creek-Orderville Watershed, UT; Intent To Prepare an Environmental Impact Statement

AGENCY: Soil Conservation Service, USDA.

ACTION: Notice of intent to prepare an environmental impact statement.

SUMMARY: Pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969; the Council on Environmental Quality Guidelines (40 CFR, part 1500); and the Soil Conservation Service Guidelines (7 CFR, part 650); the Soil Conservation Service, U.S. Department of Agriculture, gives the notice that an environmental impact statement is being prepared for the Muddy Creek-Orderville Watershed, Kane County, Utah.

FOR FURTHER INFORMATION CONTACT: Francis T. Holt, State Conservationist, Soil Conservation Service, P.O. Box 11350, Salt Lake City, Utah, 84147-0350, telephone (801) 524-5050.

SUPPLEMENTARY INFORMATION: An Environmental Assessment (EA) has been prepared for this federally assisted action. During the review of this Environmental Assessment concerns surfaced that this project would significantly impact the environment. As a result of these concerns, Frank Holt, State Conservationist, has determined that an Environmental Impact Statement (EIS) should be prepared and reviewed for this project.

Copies of the Environmental Assessment can be obtained by calling (801) 524-5054 or writing the Soil Conservation Service at P.O. Box 11350, Salt Lake City, UT 84147-0350.

The purpose of the action is watershed protection. The watershed is presently in a degrading condition, due to accelerating sheet, rill and gully erosion rates. This erosion is permanently damaging the long-term productivity of the watershed to support plant and animal life. It is also causing off-site damage by yielding salt-bearing sediment to the East Fork of the Virgin River, a part of the Colorado River System.

The Soil Conservation Service is presently seeking information and comments on the scope of issues to be addressed and alternatives and impacts to be considered in the EIS from agencies, groups and individuals.

Items that have raised a high level of concern either in the original

Environmental Assessment or from comments received from reviewers include: Erosion and sedimentation, the use of chaining as a land management procedures, water quality, plant cover, economic analysis, future grazing impacts, wildlife habitat, threatened and endangered species, archaeology sites, change in hydrologic regime, downstream salinity impacts, riparian protection, wilderness, Native American religious sites, success of vegetative treatment, diversity of plants included in the proposed seed mix and use of hazardous chemicals.

The Soil Conservation Service invites written comments and suggestions on the scope of issues related to this proposal. For most effective use in preparing the EIS, information and comments should be received in the SCS office by October 30, 1991.

A meeting to receive oral comments on the scope of issues to be addressed and alternatives and impacts to be considered will be held at the Kane County Courthouse in Kanab on Wednesday, October 16, beginning at 7 p.m.

Interested people are invited to visit with Soil Conservation Service personnel at the State Office, room 4012, Federal Building, 125 S. State St., Salt Lake City or the Field Office, 82 N. 100 East, Cedar City during the EIS process.

Another formal comment period will be held during the review of the draft EIS. The comment period on the draft EIS will begin with publication of the Notice of Availability in the Federal Register and extend for 45 days from that date. The draft is scheduled to be completed in March of 1992.

The final EIS is expected to be released in June 1992. Frank Holt, State Conservationist, who is the responsible official will then make a decision regarding this proposal after considering the comments, responses and environmental consequences discussed in the Final EIS.

(This activity is listed in the Catalog of Federal Domestic Assistance under No. 10.904—Watershed Protection and Flood Prevention—and is subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with State and local officials)

Dated: September 12, 1991.

Francis T. Holt,

State Conservationist.

[FR Doc. 91-30647 Filed 12-23-91, 8:45 am]

BILLING CODE 2410-16-M

DEPARTMENT OF COMMERCE

National Technical Information Service

Prospective Grant of Exclusive Patent License

This is notice in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i) that the National Technical Information Service (NTIS), U.S. Department of Commerce, is contemplating the grant of an exclusive license in the United States to practice the invention embodied in U.S. Patent 4,416,871, "Inhibition by Peptides of Tolerance to and Physical Dependence on Morphine" to Bio-Fine Pharmaceuticals, Inc., having a place of business at Las Vegas, NV. The patent rights in this invention have been assigned to the United States of America.

The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within sixty days from the date of this published Notice, NTIS receives written evidence and argument which establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

The invention relates to novel compositions and to methods for inhibiting the development of tolerance to and dependence on drugs of the opioid type without substantial alteration of their analgesic effects. More particularly, the invention relates to compositions comprising opioid drugs and certain peptides and to administration of these compositions to obtain the desired inhibiting effect. In a specific aspect, the invention relates to pretreatment with certain peptides followed by daily administration of the peptide during chronic morphine treatment.

The availability of the invention for licensing was published in the Federal Register Vol 47, No. 196, p. 44605 (1982). A copy of the above-identified patent may be purchased for $1.50 from Box 9, US Patent and Trademark Office, Washington, DC 20231.

Inquiries, comments and other materials relating to the contemplated license must be submitted to Papan Devnani (telephone 703/487-4732), Center for Utilization of Federal Technology, NTIS, Box 1423, Springfield, VA 22151. Applications for a license filed in response to this notice will be treated as objections to the grant of the contemplated license. Only written comments and/or applications for a license which are received by NTIS within sixty (60) days of this notice will be considered.

Douglas J. Campion,

Center for Utilization of Federal Technology, National Technical Information Service, U.S. Department of Commerce.

[FR Doc. 91-30628 Filed 12-23-91; 8:45 am]

BILLING CODE 3510-04-M

DEPARTMENT OF DEFENSE

Meeting of the Advisory Council on Dependent's Education

AGENCY: Department of Defense Dependents Schools (DoDDS), Office of the Secretary of Defense.

ACTION: Notice of meeting.

SUMMARY: This notice sets forth the schedule and proposed agenda of a forthcoming meeting of the Advisory Council on Dependent's Education (ACDE). It also describes the functions of the Council. Notice of this meeting is required under the National Advisory Committee Act. Although the meeting is open to the public, because of space constraints, anyone wishing to attend the meeting should contact the point of contact listed below.

DATES: January 24, 1992, 9 a.m. to 4:30 p.m. and January 25, 1992, 9 a.m. to 3 p.m.

ADDRESSES: January 24, The Pentagon, room 3E869, Washington, DC; January 25, Embassy Suites Hotel, Adams Morgan Room, 1402 Eads Street, Arlington, Virginia.

FOR FURTHER INFORMATION CONTACT: Ms Marilyn Witcher, Public Affairs Officer, DoD Dependents Schools, 1225 Jefferson Davis Highway, Crystal Gateway #2, suite 1500, Arlington, Virginia 22202; Telephone number: 703-746-7846.

SUPPLEMENTARY INFORMATION: The Advisory Council on Dependents' Education is established under title XIV, section 1411, of Public Law 95-561, Defense Dependents' Education Act of 1978, as amended by title XII, section 1204(b)(3)-(5), of Public Law 99-145, Department of Defense Authorization Act of 1986 (20 U.S.C., Chapter 25A, section 929, Advisory Council on Dependents' Education). The Council is cochaired by designees of the Secretary of Defense and the Secretary of Education. In addition to a representative of each of the Secretaries, 12 members are appointed jointly by the Secretaries. Members include representatives of educational institutions and agencies, professional

employee organizations, unified military commands, school administrators, parents of DoDDS students, and one DoDDS student. The Director, DoDDS, serves as the Executive Secretary of the Council. The purpose of the Council is to advise the Secretary of Defense and the DoDDS Director about effective educational programs and practices that should be considered by DoDDS and to perform other tasks as may be required by the Secretary of Defense. The agenda includes discussions about the national goals for education, academic achievement encouragement, education of handicapped dependents, communications throughout the system, increased parental involvement, results of the biennial parent survey, drawdown planning, and responses to the recommendations made by the Council during its July meeting.

Dated: December 18, 1991.

L. M. Bynum,

Alternate OSD Federal Register Liason Officer, Department of Defense.

[FR Doc. 91-30677 Filed 12-23-91; 8:45 am]

BILLING CODE 3810-01-M

Department of the Army

Army Science Board; Closed Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), announcement is made of the following Committee Meeting:

Name of the Committee: Army Science Board (ASB).

Dates of the Meeting: 6-7 January 1992.

Time: 0800-1600.

Place: Pentagon, Washington, DC.

Agenda: The Army Science Board (ASB) Ad Hoc Subgroup on the Comanche International will meet for discussions on the mission of the group, issues surrounding the development, and plans for future operations of the group. This meeting will be closed to the public in accordance with section 552b(c) of title 5, U.S.C., specifically subparagraphs (1) and (4) thereof, and title 5, U.S.C., appendix 2, subsection 10(d). The classified and unclassified matters and proprietary information to be discussed is so inextricably intertwined so as to preclude opening any portion of the meeting. The ASB Administrative Officer, Sally Warner, may be contacted for further information (703) 695-0781.

Sally A. Warner,

Administrative Officer, Army Science Board.

[FR Doc. 91-30736 Filed 12-23-91; 8:45 am]

BILLING CODE 3710-08-M

Notice of Open Meeting

AGENCY: Board of Visitors, United States Military Academy, DoD. In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92-463), announcement is made of the following meeting:

Name of Committee: Board of Visitors, United States Military Academy.

Date of Meeting: 3 February 1992.

Place of Meeting: Washington, DC.

Start Time of Meeting: 9 a.m.

Proposed Agenda: Election of officers; selection of Executive Committee; scheduling of meetings for remainder of year; and identification of areas of interest for 1992. All proceedings are open.

FOR FURTHER INFORMATION CONTACT: Lieutenant Colonel Stephen R. Furr, United States Military Academy, West Point, NY 10996-5000, (914) 938-2626.

Kenneth L. Denton,

Army Federal Register Liaison Officer.

[FR Doc. 91-30618 Filed 12-23-91; 8:45 am]

BILLING CODE 3710-08-M

DEPARTMENT OF EDUCATION

National Advisory Council on Educational Research and Improvement; Meeting

AGENCY: National Advisory Council on Educational Research and Improvement, Education.

ACTION: Full council meeting of the National Advisory Council on Educational Research and Improvement.

SUMMARY: This notice sets forth the schedule and proposed agenda of a forthcoming meeting of the National Advisory Council on Educational Research and Improvement. This notice also describes the functions of the Council. Notice of this meeting is required section 10(a)(2) of the Federal Advisory Committee Act.

DATES AND TIMES: January 14, 1992, 9 a.m. to 5 p.m. Meeting will take place in Munzer Hall Conference Room, Defense Language Institute, Monterey, California. Meeting will continue at the Monterey Marriott, Los Angeles Room, Mezzanine Level, on January 15, 9 a.m.—5 p.m., January 16, 1:30 p.m.—6 p.m., and January 17, 8 a.m.—4:30 p.m.

ADDRESSES: Defense Language Institute, Building 618, The Presidio, Monterey, CA 93944-5006. Monterey Marriott, 350 Calle Principal, Monterey, CA 93940.

FOR FURTHER INFORMATION CONTACT: Mary Grace Lucier, Executive Director, National Advisory Council on Educational Research and Improvement, 330 C Street, SW., Washington, DC 20202-7579, (202) 732-4504.

SUPPLEMENTARY INFORMATION: The National Advisory Council on Educational Research and Improvement is established under section 405 of the 1972 Education Amendments, Public Law 92-318, as amended by the Higher Education Amendments of 1986, Public Law 99-498, (20 U.S.C. 1221e). The Council is established to advise the President, the Secretary of Education and the Congress on policies and activities carried out by the Office of Educational Research and Improvement (OERI).

The meeting of the Council is open to the public. Individuals who wish to attend the portion of the meeting at the Defense Language Institute are advised to contact the Council office and leave their names and affiliations no later than January 10, 1992. The proposed agenda includes briefings by personnel of the Defense Language Institute (January 14); speakers on the topics of global competitiveness and second language learning (January 15); formulation of recommendations by Council members (January 16); and presentations on school-business partnerships and California's multicultural history curriculum (January 17).

Records are kept of all Council Proceedings and are available for public inspection at the Office of the National Advisory Council on Educational Research and Improvement, 330 C Street, SW., suite 4076, Washington, DC 20202-7579, from 9 a.m. to 5 p.m. Monday through Friday.

Dated: December 19, 1991.

Mary Grace Lucier,

Executive Director.

[FR Doc. 91-30681 Filed 12-23-91; 8:45 am]

BILLING CODE 4000-01-M

Office of Postsecondary Education

State Student Incentive Grant Program

AGENCY: Department of Education.

ACTION: Notice of the closing date for the receipt of state applications for fiscal year 1992.

SUMMARY: The Secretary gives notice of the closing date for the receipt of State applications for fiscal year 1992 funds under the State Student Incentive Grant (SSIG) Program. This program, through matching formula grants to States for student awards, provides a nationwide delivery system of grants for students with substantial financial need.

A State that desires to receive SSIG funds for any fiscal year must have an agreement with the Secretary as provided for under the authorizing law and must submit an application through the State agency that administered its SSIG Program on July 1, 1985.

The Secretary is authorized to accept applications from the 50 States, the District of Columbia, Puerto Rico, American Samoa, Guam, the Commonwealth of Northern Mariana Islands, the Virgin Islands, and the Republic of Palau, provided it remains a trust territory. (The future eligibility of the Republic of Palau will be determined by the provisions of the Compact of Free Association.) Authority for this program is contained in sections 415A through 415E of the Higher Education Act of 1965, as amended (HEA). (20 U.S.C. 1070c–1070c–4).

CLOSING DATE FOR TRANSMITTAL OF APPLICATIONS: An application for fiscal year 1992 SSIG Program funds must be mailed or hand-delivered by February 24, 1992.

APPLICATIONS DELIVERED BY MAIL: An application sent by mail must be addressed to the U.S. Department of Education, Office of Student Financial Assistance, 400 Maryland Avenue, SW., Washington, DC 20202–5447, Attention: Mr. Fred Sellers, Chief, State Grant Section, room 4018, ROB #3.

An applicant must show proof of mailing consisting of one of the following: (1) A legibly dated U.S. Postal Service postmark; (2) a legible mail receipt with the date of mailing stamped by the U.S. Postal Service; (3) a dated shipping label, invoice, or receipt from a Commercial Carrier; or (4) any other proof of mailing acceptable to the Secretary of Education.

If an application is sent through the U.S. Postal Service, the Secretary does not accept either of the following as proof of mailing: (1) A private metered postmark; or (2) a mail receipt that is not dated by the U.S. Postal Service. An applicant should note that the U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, an applicant should check with its local post office. The Department of Education encourages applicants to use registered or at least first-class mail.

Each late applicant will be notified that it cannot be assured that its application will be considered for fiscal year 1992 funding.

APPLICATIONS DELIVERED BY HAND: An application that is hand-delivered must be taken to the U.S. Department of Education, Office of Student Financial Assistance, 7th and D Streets, SW., room 4018, GSA Regional Office Building #3, Washington, DC. Hand-delivered applications will be accepted between 8 a.m. and 4:30 p.m. daily (Washington, DC time), except Saturdays, Sundays, and Federal holidays.

An application that is hand-delivered will not be accepted after 4:30 p.m. on the closing date.

PROGRAM INFORMATION: The Secretary requires an annual submission of an application for receipt of SSIG funds. In preparing an application, each State agency should be guided by the table of allotments provided in the application package.

State allotments are determined by the statutorily mandated formula and are not subject to negotiations. The States may also request a share of reallotments, in addition to their basic allotments, contingent upon the availability of such funds from allotments to any States unable to use all their basic allotments. In fiscal year 1991, all 50 States, the District of Columbia, Puerto Rico, the Virgin Islands, and Guam participated in the SSIG assistance delivery network.

APPLICATION FORM: The required application form for receiving SSIG Program funds will be mailed to officials of appropriate State agencies at least 30 days before the closing date. Applications must be prepared and submitted in accordance with the HEA and the program regulations cited in this notice. The Secretary strongly urges that applicants not submit information that is not requested.

APPLICABLE REGULATIONS: The following regulations are applicable to the SSIG Program:

(1) The SSIG Program regulations (34 CFR part 692).

(2) The Education Department General Administrative Regulations (EDGAR) in 34 CFR part 76 (State-Administered Programs), part 77 (Definitions that Apply to Department Regulations), part 80 (Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments), part 82 (New Restrictions on Lobbying) and part 85 (Governmentwide Debarment and Suspension (Nonprocurement) and Governmentwide Requirements for Drug-Free Workplace (Grants)).

(3) The regulations in 34 CFR part 604 that implement section 1203 of the HEA (Federal-State Relationship Agreements).

(4) The Student Assistance General Provisions in 34 CFR part 668.

FOR FURTHER INFORMATION: For further information contact Mr. Fred Sellers, Chief, State Grant Section, Office of Student Financial Assistance, U.S. Department of Education, Washington, DC 20202–5447; telephone (202) 708–4607. (20 U.S.C. 1070c–1070c–4).

Dated: December 16, 1991.

(Catalog of Federal Domestic Assistance Number 84.069, State Student Incentive Grant Program)

Carolynn Reid-Wallace,

Assistant Secretary for Postsecondary Education.

[FR Doc. 91–30629 Filed 12–23–91; 8:45 am]

BILLING CODE 4000–01–M

DEPARTMENT OF ENERGY

Financial Assistance to the Colorado Department of Health for Administration and Enforcement of a State Hazardous Waste Management Program

AGENCY: Rock Flats Office, DOE.

ACTION: Notice of intent to award noncompetitive financial assistance to the Colorado Department of Health.

SUMMARY: Pursuant to the statutory authorities of section 646 of the Department of Energy Authorization Act (Pub. L. 95–91) and the Federal Grant and Cooperative Agreement Act of 1977 (Pub. L. 97–258), the Department of Energy, Rocky Flats Office, gives notice of its plan to award approximately $500,000 to the Colorado Department of Health for reimbursement of costs incurred in the first year of a five-year Interagency Agreement (IAG) between the Department of Energy (DOE), Environmental Protection Agency (EPA), and Colorado Department of Health (CDH). The State of Colorado received authorization from EPA to administer and enforce a State hazardous waste management program. CDH is the State agency designated to oversee the assessment and remediation activities at Rocky Flats Plant which include permitting and closure plans, approval of statements of work and work plans, the selection of remedial actions for each operable unit, the taking of samples, ensuring that work is being performed properly and in accordance with the terms of the IAG.

FOR FURTHER INFORMATION CONTACT: Dorothy Gross, Contract Specialist, U.S. DOE, Rocky Flats Office, Contracts and Services Division, P.O. Box 928, Golden, CO 80402–0928, Grant Number DE–FG34–92RF00215.

Robert M. Nelson, Jr.,

Manager.

[FR Doc. 91–30706 Filed 12–23–91; 8:45 am]

BILLING CODE 6450–01–M

Federal Energy Regulatory Commission

[Project No. 120-007, et al.]

Hydroelectric Applications; Southern California Edison Co., et al.; Applications

Take notice that the following hydroelectric applications have been filed with the Commission and are available for public inspection.

1a. *Type of Application:* Amendment of License.

b. *Project No.:* 120-007.

c. *Date Filed:* 11/29/91.

d. *Applicant:* Southern California Edison Company.

e. *Name of Project:* Big Creek No. 3 Project.

f. *Location:* On the San Joaquin River, in Fresno, Tulare, and Kern Counties, California. The project affects lands of the United States within the Sierra National Forest.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Mr. E. Martinez, Manager of Hydro Generation, Southern California Edison Company, P.O. Box 800, Rosemead, CA 91770 (818) 302–1564.

i. *FERC Contact:* Paul Shannon, (202) 219–2866.

j. *Comment Date:* January 31, 1992.

k. *Description of Amendment:* Southern California Edison Company (SCEC) requests approval of an as-built exhibit M for the Big Creek No. 3 Project. The as-built exhibit M states that the generator for Unit 5 was installed in 1980 at a capacity of 36,000-kW. This is 1000-kW greater than the authorized capacity of the unit. Also, between 1979 and 1985, SCEC rewound the remaining four generators. These factors increased the installed generating capacity of the project from the authorized 141,500-kW to 177,450-kW. Between 1982 and 1985, SCEC also renovated four of the five project turbines by replacing their turbine runners and seal rings. These renovations increased the total hydraulic capacity of the project from the authorized 3,095 cfs to 3,450 cfs.

1. *This notice also consists of the following standard paragraphs: B, C, and D2.*

2a. *Type of Application:* Transfer of License.

b. *Project No.:* 2899–025.

c. *Date filed:* October 28, 1991.

d. *Applicants:* Twin Falls Canal Company (Twin), North Side Canal Company (North), and Milner Dam, Inc. (Milner).

e. *Name of Project:* Milner Hydroelectric Project.

f. *Location:* On lands administered by the Bureau of Land Management on the Twin Falls Main Canal and Snake River in Twin Falls, Cassia, Jerome, and Minidoka Counties, Idaho.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Twin Falls Canal Company, P.O. Box 326, Twin Falls, ID 83303–0326, (208) 733–6731; North Side Canal Company, Ltd., 921 North Lincoln Avenue, Jerome, ID 83338, (202) 324–2319.

i. *FERC Contact:* Mr. Michael Strezelecki, (202) 219–2827.

j. *Comment Date:* February 3, 1992.

k. *Description of Project:* On December 15, 1988, a license was issued to Twin and North for the construction, operation, and maintenance of the Milner Hydroelectric Project. The project consists of the Milner dam and reservoir, a canal, a forebay, a penstock, and two powerhouses with a total installed capacity of 58 MW. Twin and North request approval to transfer the license to Milner.

1. *This notice also consists of the following standard paragraphs:* B and C.

3a. *Type of Application:* Amendment to Major License Application.

b. *Project No.:* 4715–003.

c. *Dated filed:* July 2, 1990.

d. *Applicant:* Long Lake Energy Corporation.

e. *Name of Project:* Felts Mills.

f. *Location:* On the Black River in Jefferson County, New York.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* F. Joseph Feyder, 420 Lexington Ave., suite 540, New York, NY 10170, (212) 986–0440.

i. *FERC Contact:* Charles T. Raabe (202) 219–2811.

j. *Deadline Date:* February 3, 1992.

k. *Description of Project:* The project, as currently proposed, would consist of a Lower Dam development and an Upper Dam Development. The two developments are about 1.1 miles apart. The existing Middle Dam, except the submerged wood crib dam, would be demolished. The existing abandoned mill at the Lower Dam would also be demolished.

(A) The Lower Dam development would consist of: (1) An about 2,160-foot-long and 25.5-foot-high concrete gravity dam, consisting of a right bank section, a fuse plug dike section, an auxiliary gated spillway section, a powerhouse section, and a left bank retaining wall section; (2) a reservoir with water surface area of 142 acres, a gross storage capacity of 850 acre-feet, and a normal water surface elevation of 588.5 feet; (3) a forebay approximately 70 feet long, 70 feet wide, and 36 feet deep; (4) a powerhouse containing two generating units with a total installed capacity of 8,133 kW; (5) a tailrace approximately 600 feet long and 70 feet wide; (6) a powerhouse yard with security fence; (7) an about 260-foot-long access road to the powerhouse; (8) a rockfill embankment on the south shore; (9) a 13.8-kV transmission line, approximately 1,600 feet long; and (10) appurtenant facilities.

(B) The Upper Dam development would consist of: (1) An about 510-foot-long and 26.5-foot-high concrete gravity dam, consisting of an existing modified spillway section with canoe chute, a new gated spillway section, an approach chanel spillway section, a gated ice sluice section, and a powerhouse section; (2) a reservoir with a water surface area of 220 acres, a gross storage capacity of 1,100 acre-feet, and a water surface elevation of 608.9 feet; (3) an about 390-foot-long, 70-foot-wide, and 50-foot-deep power canal with trash boom and security fence; (4) a powerhouse containing two generating units with a total installed capacity of 5,030 kW; (5) a tailrace; approximately 100 feet long and 70 feet wide; (6) an about 140-foot-long access road to the powerhouse; (7) an about 90-foot span bridge across the power canal; (8) a 13.8-kV transmission line approximately 10,560 feee long; and (9) appurtenant facilities.

The project would have a total installed capacity of 13,163 kW. The applicant estimates that the average annual generation would be 62,570,000 kWh.

1. *This notice also consists of the following standard paragraphs:* A4, and B1.

m. *Availability Location of Application:* A copy of the application, as amended and supplemented, is available for inspection and reproduction at the Commission's Public Reference and Files Maintenance Branch, located at 941 North Capitol Street, NE., room 3104, Washington, DC 20426, or by calling (202) 208–1371.

4a. *Type of Application:* Surrender of License.

b. *Project No.:* 8418–004

c. *Dated filed:* November 20, 1991.

d. *Applicants:* U.S. Tungsten Corporation.

e. *Name of Project:* Pine Creek Water Power Project.

f. *Location:* On an unnamed tributary of Morgan Creek partly within Inyo National Forest in Inyo County, California.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Tim Scott, General Manager, U.S. Tungsten Corporation, Pine Creek Road, route 2, Bishop, California 93514, (619) 387–2501.

i. *FERC Contact:* Mr. Michael Strzelecki, (202) 219–2827.

j. *Comment Date:* January 27, 1992.

k. *Description of Project:* On January 31, 1986, a license was issued to the Umetco Minerals Corporation for the construction, operation, and maintenance of the Pine Creek Water Power Project. On March 19, 1987, the license was transferred to the U.S. Tungsten Corporation. The project would utilize water emanating from fissures formed during the Licensee's tunneling and mining operations and would consist of two penstocks, two powerhouses, and a tailrace.

The license surrender is requested because the project is not financially feasible.

1. *This notice also consists of the following standard paragraphs:* B and C.

5a. *Type of Application:* Application to Amend exhibit R (recreation plan) of the Project License.

b. *Project No.:* 10254–012.

c. *Date Filed:* November 21, 1991.

d. *Applicant:* Consolidated Hydro Southeast Inc.

e. *Name of Project:* Upper Pelzer Hydroelectric Project.

f. *Location:* Anderson County, South Carolina.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contract:* Kathy Dority, Consolidated Hydro Southeast Inc., P.O. Box 512, Greenville, SC 29602–0512, (803) 233–8567.

i. *FERC Contact:* Dan Hayes, (202) 219–2660.

j. *Comment Date:* January 22, 1992.

k. *Description of Project:* Consolidated Hydro Southeast Inc. has filed an application with the Federal Energy Regulatory Commission to amend its project recreation plan. The licensee proposes to delete a parking area at its Upper Pelzer Fishing Access Area from its recreation plan. Consultation with the S.C. Highway Department has revealed that the parking area is unsuitable for parking and pedestrian use due to the sharp curves in the road at that area. Pedestrian access to the river will be maintained, but parking will not be permitted at the site.

l. *This notice also consists of the following standard paragraphs:* B, C, and D2.

6a. *Type of Application:* Minor License.

b. *Project No.:* 10552–002.

c. *Date Filed:* May 13, 1991.

d. *Applicant:* Contractors Power Group, Inc.

e. *Name of Project:* Mile 28 Water Power Project.

f. *Location:* On the Bureau of Reclamation's Milner-Gooding Canal, off Snake River, in Jerome County, Idaho. Section 7, T8S, R20E, Boise Meridian.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Mr. John J. Straubhar, P.E., P.O. Box 820, Twin Falls, ID 83303, (202) 788–0484.

i. *FERC Contact:* Mr. Surender M. Yepuri, P.E., (202) 219–2847.

j. *Deadline Date:* February 17, 1992.

k. *Status of Environmental Analysis:* This application is not ready for an environmental analysis at this time—see attached paragraph D8.

l. *Description of Project:* The proposed project, within the canal with the exception of the transmission line, would consist of: (1) A 240-foot-long concrete diversion/overflow spillway; (2) a 34-foot-wide, 55-foot-long powerhouse containing two Kaplan Turbine/generator units with a total rated capacity of 1.5 MW; (3) a 1200-foot-long tailrace channel; (4) a 150-foot-long, 35-kV transmission line connecting to a local distribution line; and (4) appurtenant facilities.

The project would have an estimated annual output of 5.8 GWh and would cost $1,700,000 in 1991 dollars to construct.

m. *Purpose of Project:* Power generated would be sold to a local utility.

n. *This notice also consists of the following standard paragraphs:* A2, A9, B1, and D8.

o. *Available Locations of Application:* A copy of the application, as amended and supplemented, is available for inspection and reproduction at the Commission's Public Reference and Files Maintenance Branch, located at 941 North Capitol Street, NE., room 3104, Washington, DC 20426, or by calling (202) 208–1371. A copy is also available for inspection and reproduction at (1) J.J. Straubhar, 1061 Blue Lakes North, suite 204, Twin Falls, ID 83303; telephone (208) 734–8633; and (2) Jerome Public Library, Jerome, ID.

7a. *Type of Application:* Minor License.

b. *Project No.:* 11128–000.

c. *Date filed:* April 10, 1991.

d. *Applicant:* Odell Hydroelectric Co.

e. *Name of Project:* Brooklyn.

f. *Location:* On the Upper Ammonoosuc River in the community of Groveton in the Town of Northumberland, in Coos County, New Hampshire.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Mr. Gregory Cloutier, RR 1, Box 2, Jefferson, NH 03583, (603) 586–4506.

i. *FERC Contact:* Ms. Julie Bernt, (202) 219–2814.

j. *Deadline Date:* Deadline set by paragraph D9.

k. *Status of Environmental Analysis:* This application is ready for environmental analysis at this time—see attached paragraph D9.

l. *Description of Project:* The proposed project would consist of: (1) An existing 4-foot-high rock-filled, timber crib Red Dam; (2) an existing reservoir with a surface area of 66 acres at surface elevation 882.6 m.s.l. and a storage capacity of 200 acre-feet; (3) an existing 16-foot-high rock-filled, timber crib Brooklyn Dam; (4) an existing reservoir with a surface area of 26 acres at elevation 877.8 m.s.l. and a storage capacity of 50 acre-feet; (5) an existing powerhouse at Brooklyn Dam containing 2 proposed generating units with a total rated capacity of 530 kW; (6) a tailrace; (7) a proposed 150-foot-long transmission line; and, (8) appurtenant facilities. The existing dams and facilities are owned by James River Paper Company, Inc. The average annual energy generation is estimated to be 2.190 MWh and the estimated cost of redevelopment of these facilities is $880,000.

m. *Purpose of Project:* Power produced would be sold to a local power company.

n. *This notice also consists of the following standard paragraphs:* A4 and D9.

o. *Available Locations of Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference and Files Maintenance Branch, located at 941 North Capitol Street, NE., room 3104, Washington, DC 20426, or by calling (202) 208–1371. A copy is also available for inspection and reproduction at the offices of Odell Hydroelectric Co., RR 1, Box 2, Jefferson, NH 03583 or by calling (603) 586–4506.

8a. *Type of Application:* Minor License.

b. *Project No.:* 11132–000.

c. *Date filed:* April 26, 1991.

d. *Applicant:* Consolidated Hydro Maine, Inc.

e. *Name of Project:* Eustis Dam.

f. *Location:* On the North Branch of the Dead River near Eustis in Franklin County, Maine.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Mr. Wayne E. Nelson, RR 2, Box 690 H Industrial Ave., Sanford, ME 04073, (207) 490–1980.

i. *FERC Contact:* Ms. Julie Bernt (202) 219–2814.

j. *Deadline Date:* January 24, 1992.

k. *Status of Environmental Analysis:* This application is not ready for environmental analysis at this time—see attached paragraph E.

l. *Description of Project:* The proposed project would consist of: (1) An existing 15-foot-high concrete gravity dam owned by the applicant, (2) a 178-foot-long ogee type spillway; (3) an existing reservoir with a surface area of 73.5 acres at surface elevation 1,161 feet m.s.l. and a storage capacity of 570 acre-feet; (4) an existing powerhouse containing one generating unit with a rated capacity of 250 kW; (5) a bedrock tailrace; and (6) appurtenant facilities. The average annual energy generation is estimated to be 1,600 MWh. There is no new construction; therefore, there are no project costs.

m. *Purpose of Project:* Power produced would be sold to a local power company.

n. *This notice also consists of the following standard paragraphs:* A2, A9, B2, and E.

9a. *Type of Application:* Minor License.

b. *Project No.:* 11142–000.

c. *Date Filed:* May 3, 1991.

d. *Applicant:* Consolidated Hydro Maine, Inc.

e. *Name of Project:* Estes Lake Dam.

f. *Location:* On the Mousam River, York County, Maine.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Mr. Wayne E. Nelson, RR2 Box 690 H Industrial Avenue, Sanford, ME 04073, (207) 490–1980.

i. *FERC Contact:* Michael Dees (202) 219–2807.

j. *Deadline Date:* January 22, 1992.

k. *Status of Environmental Analysis:* This application is not ready for environmental analysis at this time—see attached standard paragraph E.

l. *Description of Project:* The existing project consists of the following: (1) A concrete-capped cut stone dam eight to 40 feet high and 726 feet long, with a left abutment dike about six feet high and 115 feet long; (2) an impoundment with a surface area of 474 acres and a normal water surface elevation of 214 feet msl; (3) a wooden/brick and masonry powerhouse housing two hydropower units with a combined capacity of 775 kW; (4) a tailrace excavated from bedrock with cut stone sidewalls; (5) a 2,000 kV.A transmission line five miles long; and (6) appurtenant facilities. The average annual energy generation is 3.8 GWh and is sold to Central Maine Power Company. The project facilities are owned by the applicant.

m. *Purpose of Project:* The purpose of the project is to generate electric energy for sale.

n. *This notice also consists of the following standard paragraphs:* A2, A9, B2 and E.

o. *Available Location of Application:* A copy of the application, as amended and supplemented, is available for inspection and reproduction at the Commission's Public Reference and Files Maintenance Branch, located at 941 North Capitol Street, NE., room 3104, Washington, DC, 20426, or by calling (202) 208–1371.

p. Federal, State, and local agencies may obtain a copy of the application directly from the applicant.

10a. *Type of Application:* Major License.

b. *Project No.:* 11151–000.

c. *Date Filed:* May 28, 1991. This notice supersedes the notice issued November 14, 1991, for this project.

d. *Applicant:* Energy Alternatives of North America, Inc.

e. *Name of Project:* Williams Dam.

f. *Location:* On the East Fork of the White River near Bedford in Lawrence County, Indiana.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Mr. C. Scott Hitchcock, P.O. Box 21, Kohler, WI 53044, (414) 452–2624.

i. *FERC Contact:* Ms. Julie Bernt, (202) 219–2814.

j. *Deadline Date:* Dealine set by paragraph D9.

k. *Status of Environmental Analysis:* This application is ready for environmental analysis at this time—see attached paragraph D9.

l. *Description of Project:* The proposed project would consist of: (1) An existing 25-foot-high concrete dam owned by the State of Indiana; (2) a reservoir with a surface area of 200 acres at surface elevation of 475 feet m.s.l. and a storage capacity of 1,000 acre-feet; (3) a new powerhouse with intake openings at an existing powerhouse substructure containing four generating units each rated at 470 kW; (4) a 1¾–miles long transmission line; and (5) appurtenant facilities. The project would have an estimated annual output of 10,660 MWh and would cost $2,800,000 to construct.

m. *Purpose of Project:* The power produced would be sold to a local power company.

n. *This notice also consists of the following standard paragraphs:* A4 and D9.

o. *Available Locations of Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference and Files Maintenance Branch located at 941 North Capitol Street, NE., room 3104, Washington, DC 20426, or by calling (202) 208–1371. A copy is also available for inspection and reproduction from Mr. Hitchcock at P.O. Box 21, Kohler, WI or by calling (414) 452–2624.

11a. *Type of Application:* Minor License.

b. *Project No.:* 11169–000.

c. *Date Filed:* July 25, 1991.

d. *Applicant:* H&H Properties.

e. *Name of Project:* Avalon Dam.

f. *Location:* On the Mayo River, Rockingham County, North Carolina.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791 (a)-825(r).

h. *Applicant Contact:* Mr. Tim Henderson, H&H Properties, 1240 Springwood Church Road, Gibsonville, NC 27249, (919) 449–5054.

i. *FERC Contact:* Mary C. Golato (202) 219-2804.

j. *Deadline Date:* February 13, 1992.

k. *Status of Environmental Analysis:* This application is ready for environmental analysis at this time—see attached D4.

l. *Description of Project:* The proposed Avalon Dam Hydroelectric Project consists of three new turbine-generator units, and their accessory control and transmission equipment, installed at an existing dam, power canal, penstock and powerhouse development.

In detail, the project would consist of: (1) An existing masonry gravity spillway dam about 360 feet long and 22 feet high maximum, to be crested with new 1-foot-high flashboards; (2) a left abutment masonry dam about 40 feet long and 33 feet high maximum; (3) a right abutment masonry headgate structure, about 56 feet long and 30 feet high; (4) a reservoir with a surface area of about 12.1 acres and gross storage of 126 acre-feet at a level of 625.5 mean sea level; (5) an existing power canal about 1,800 feet long, 20 to 26 feet wide, and 8 to 12 feet deep, connecting the headgate structure to; (6) an existing masonry intake for a steel penstock 9 feet in diameter and 160 feet long; (7) an existing masonry powerhouse 24 feet wide, 70 feet long and 25 feet high; (8) new powerhouse equipment consisting of one single-runner Francis unit and generator rated at 200 kilowatts (kW), and a second double-runner Francis unit and generator rated at 580 kW, both units discharging into an existing tailrace; (9) a new instream flow turbine-generator unit related 60 kW, located at the upstream end of the power canal, and discharging at the toe of the dam; (10) a

12.4-kilovolt transmission line about 1,280 feet long; and (11) appurtenant facilities.

m. *Purpose of Project:* Generated power would be used solely by Duke Power Company.

n. *This notice also consists of the following standard paragraphs:* A3, A9, B1, and D4.

o. *Available Locations of Applications:* A copy of the application, as amended and supplemented, is available for inspection and reproduction at the Commission's Public Reference and Files Maintenance Branch, located at 941 North Capitol Street, NE., room 3104, Washington, DC 20426, or by calling (202) 208-1371. A copy is also available for inspection and reproduction at Mr. Tim Henderson, H&H Properties, 1240 Springwood Church Road, Gibsonville, NC 27249, (919) 449–5054 and at May Memorial Library, 342 South Spring Street, Burlington, NC 27215.

12a. *Type of Application:* Preliminary Permit.

b. *Project No.:* 11179–000.

c. *Date Field:* August 27,1991.

d. *Applicant:* Faulkner Land and Livestock Inc.

e. *Name of Project:* Freeway Drop.

f. *Location:* At the Little Wood River, on lands administered by the Bureau of Land Management, on the North Side Canal Company's canal system, in Elmore County, Idaho. Township 5 S Range 11, 12, 13 and 14 E Sections 20, 23, 24, 25, 26, 27, 28, 29, and 30.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791(a)-825(r).

h. *Applicant Contact:* Mr. Michael Arkoosh, 714 Third Avenue East, Goodling, ID 83330, (208) 934–4817.

i. *FERC Contact:* Michael Spender at (202) 219–2846.

j. *Comment Date:* Februay 6, 1992.

k. *Description of Project:* The proposed project would consist of: (1) An existing 6-foot-high concrete dam on the Little Wood River; (2) an existing 18.5-mile-long, 16-foot-wide canal; (3) a 10-foot-high earthen diversion dam on the canal; (4) a 36-inch-diameter, 14,000-foot-long penstock; (5) a powerhouse containing a generating unit with a capacity of 1,575 kW and an estimated annual generation of 7.5 GWh; and (6) a 250-foot-long transmission line.

No new access road will be needed to conduct the studies. The applicant estimates that the cost of the studies to be conducted under the preliminary permit would be $10,000.

l. *Purpose of Project:* Project power will be sold to Idaho Power Company.

m. *This notice also consists of the following standard paragraphs:* A5, A7, A9, A10, B, C, and D2.

13a. *Type of Application:* Preliminary Permit.

b. *Project No.:* 11201–000.

c. *Date filed:* November 6, 1991.

d. *Applicant:* Peak Power Corporation.

e. *Name of Project:* Butte Pumped Storage Hydroelectric Project.

f. *Location:* At the abandoned Berkeley Pit copper mine superfund site within the city of Butte, in Silver Bow County, Montana. T3N, R7W in sections 6, 7, 8, 17, and 18.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Mr. Rick S. Koebbe, Vice President, Peak Power Corporation, 10 Lombard Street, Suite 410, San Francisco, CA 94111, (415) 362–0887.

i. *FERC Contact:* Michael Strzelecki, (202) 219–2827.

j. *Comment Date:* February 14, 1991.

k. *Description of Project:* The proposed pumped storage project would consist of: (1) A 60-foot-high earthen dam and 63-acre upper reservoir at the abandoned mine dump area; (2) a 10-foot-diameter, 3,000-foot-long penstock connecting the upper reservoir with the lower reservoir; (3) an 80-acre lower reservoir utilizing Montana Resource's existing abandoned Berkeley mine pit; (4) a powerhouse containing two 50-MW generating units; (5) a 4,000-foot-long, 100-kV transmission line interconnecting with an existing Montana Power Company transmission line; (6) a water treatment facility; and (7) appurtenant facilities. The water source for the proposed project would be groundwater and mining wastewater effluent.

No new access roads will be needed to conduct the studies. The approximate cost of the studies would be $200,000.

1. *This notice also consists of the following standard paragraphs:* A5, A7, A9, A10, B, C, and D2.

14a. *Type of Application:* Preliminary Permit.

b. *Project No.:* 11202–000.

c. *Date filed:* November 7, 1991.

d. *Application:* Willard C. Lipe, William M. Allen, Jr., and James M. Jackson.

e. *Name of Project:* Edwards Falls Project.

f. *Location:* On Limestone Creek at Edwards Falls, in the Town of Manlius, in the County of Onondaga, New York.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* William M. Allen, Jr., R.D.1, Cardner Road, New Woodstock, NY 13122 (315) 662–3125.

i. *FERC Contact:* Mary C. Golato (202) 219–2804.

j. *Comment Date:* February 21, 1992.

k. *Description of Project:* The proposed project would consist of the following facilities: (1) An existing 19-foot-high dam; (2) an existing mill pond at the dam approximately 4 acres in surface area, a very limited storage capacity, and a normal maximum elevation of 720 feet above mean sea level; (3) a proposed 4-foot-diameter penstock 750 feet long; (4) a new powerhouse consisting of two new turbines having a total installed capacity of 400 kilowatts; (5) a proposed 480-volt 3-phase transmission line 300 feet long; and (6) appurtenant facilities. The dam is owned by Enders Road Development Corporation and the average annual generation is estimated as 2.0 million kilowatthours. The applicant expects the cost of the studies to be minimal.

1. *This notice also consists of the following standard paragraphs: A5, A7, A9, A10, B, C, and D2.*

15a. *Type of Application:* Preliminary Permit.

b. *Project No.:* 11203–000.

c. *Date filed:* November 13, 1991.

d. *Applicant:* Blackfeet Tribe of the Blackfeet Indian Reservation.

e. *Name of Project:* Swift Dam Hydroelectric Project.

f. *Location:* Partially on Bureau of Land Management property of Birch Creek in Pondera County, Montana. T28N, R10W in sections 22, 23, 26, 27, 28, 33, and 34.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Donald G. Kittson, Blackfeet Legal Department, P.O. Box 849, Browning, MT 59417.

i. *FERC Contact:* Mr. Michael Strzelecki, (202) 219–2827.

j. *Comment Date:* February 17, 1992.

k. *Competing Application:* Swift Dam Hydroelectric Project (FERC No. 11159–000) Pondera County Canal & Reservoir Co.

1. *Description of Project:* The proposed project would consist of: (1) The existing 200-foot-high Swift dam and 500-acre Swift Reservoir owned by the Pondera County Canal & Reservoir Company; (2) a powerhouse containing two generators with a total installed capacity of 2.2 MW; (3) a 100-foot-long transmission line interconnecting with an existing Glacier Electric Cooperative transmission line; and (4) appurtenant facilities.

No new access roads will be needed to conduct the studies. The approximate cost of the studies under the permit would be $100,000.

m. *This notice also consists of the following standard paragraphs: A3, A10, B, C, and D2.*

16a. *Type of Application.* Preliminary Permit.

b. *Project No.* 11204–000.

c. *Date filed:* November 18, 1991.

d. *Applicant:* Magic Irrigators, Inc.

e. *Name of Project:* Hertzinger Hydroelectric Project.

f. *Location:* On Salmon Falls Creek, Tributary to the Snake River, in Twin Falls County, Idaho, near the town of Buhl. Township 9, Range 13 East, section 1, Boise Meridian.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* John J. Straubhar, P.E., P.O. Box 820, Twin Falls, ID 83303, (208) 734–8633.

i. *FERC Contact:* Ms. Deborah Frazier-Stutely (202) 219–2842.

j. *Comment Date:* February 13, 1991.

k. *Description of Project:* The proposed project would consist of: (1) The applicant's existing 10-foot-high 85-foot-long rock-fill dam; (2) an intake structure; (3) a 2,400-foot-long water conveyance system consisting of a 2,000-foot-long canal, a 200-foot-long flume, and a 200-foot-long penstock; (4) a powerhouse containing two generating units with a total installed capacity of 175 kilowatts; (5) a tailrace; (6) a switchyard; and (7) a 34.5 kilovolt, 2,400-foot-long transmission line tying into an existing utility line.

The applicant estimates the cost of the studies to be conducted under the preliminary permit would be $20,000. No new roads will be needed for the purpose of conducting these studies.

l. *Purpose of Project:* Project power will be sold to a local utility.

m. *This notice also consists of the following standard paragraphs:* A5, A7, A9, A10, B, C, D2.

Standard Pargraphs

A2. Development Application—Any qualified applicant desiring to file a competing application must submit to the Commission, on or before the specified deadline date for the particular application, a competing development application, or a notice of intent to file such an application. Submission of a timely notice of intent allows an interested person to file the competing development application no later than 120 days after the specified deadline date for the particular application. Applications for preliminary permits will not be accepted in response to this notice.

A3. Development Application—Any qualified development applicant desiring to file a competing application must submit to the Commission, on or before the specified comment date for the particular application, a competing development application, or a notice of intent to file such an application. Submission of a timely notice of intent allows an interested person to file the competing development application no later than 120 days after the specified comment date for the particular application. Applications for preliminary permits will not be accepted in response to this notice.

A4. Development Application—Public notice of the filing of the initial development application, which has already been given, established the due date for filing competing applications or notices of intents. Under the Commission's regulations, any competing development application must be filed in response to and in compliance with public notice of the initial development application. No competing applications or notices of intent may be filed in response to this notice.

A5. Preliminary Permit—Anyone desiring to file a competing application for preliminary permit for a proposed project must submit the competing application itself, or a notice of intent to file such an application, to the Commission on or before the specified comment date for the particular application (see 18 CFR 4.36). Submission of a timely notice of intent allows an interested person to file the competing preliminary permit application no later than 30 days after the specified comment date for the particular application. A competing preliminary permit application must conform with 18 CFR 4.30(b)(1) and (9) and 4.36.

A7. Preliminary Permit—Any qualified development applicant desiring to file a competing development application must submit to the Commission, on or before the specified comment date for the particular application, either a competing development application or a notice of intent to file such an application. Submission of a timely notice of intent to file a development application allows an interested person to file the competing application no later than 120 days after the specified comment date for the particular application. A competing license application must conform with 18 CFR 4.30(b)(1) and (9) and 4.36.

A8. Preliminary Permit—Public notice of the filing of the initial preliminary permit application, which has already been given, established the due date for filing competing preliminary permit applications or notices of intent. Any competing preliminary permit or development application or notice of intent to file a competing preliminary permit or development application must be filed in response to and in compliance with the public notice of the initial preliminary permit application. No competing applications or notices of intent to file competing applications may be filed in response to this notice. A competing license application must conform with 18 CFR 4.30(b)(1) and (9) and 4.36.

A9. Notice of intent—A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, include an unequivocal statement of intent to submit, if such an application may be filed, either (1) a preliminary permit application or (2) a development application (specify which type of application), and be served on the applicant(s) named in this public notice.

A10. Proposed Scope of Studies under Permit—A preliminary permit, if issued, does not authorize construction. The term of the proposed preliminary permit would be 36 months. The work proposed under the preliminary permit would include economic analysis, preparation of preliminary engineering plans, and a study of environmental impacts. Based on the results of these studies, the Applicant would decide whether to proceed with the preparation of a development application to construct and operate the project.

B. Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of the Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

B1. or B2. Protests or Motions to Intervene—Anyone may submit a protest or a motion to intervene in accordance with the requirements or Rules of Practice and Procedure, 18 CFR 385.210, 385.211, and 385.214. In determining the appropriate action to take, the Commission will consider all protests filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any protests or motions to intervene must be received on or before the specified deadline date for the particular application.

C. Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS", "NOTICE OF INTENT TO FILE COMPETING APPLICATION",

"COMPETING APPLICATION", "PROTEST", "MOTION TO INTERVENE", as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426. An additional copy must be sent to Director, Division of Project Review, Federal Energy Regulatory Commission, room 1027, at the above-mentioned address. A copy of any notice of intent, competing application or motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

D2. Agency Comments—Federal, State, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

D4. Filing and Service of Responsive Documents—The application is ready for environmental analysis at this time, and the Commission is requesting comments, reply comments, recommendations, terms and conditions, and prescriptions.

The Commission directs, pursuant to § 4.34(b) of the regulations (see Order No. 533 issued May 8, 1991, 56 FR 23108, May 20, 1991) that all comments, recommendations, terms and conditions and prescriptions concerning the application be filed with the Commission within 60 days from the issuance date of this notice (60 days from December 6, 1991 for Project No. 11169). All reply comments must be filed with the Commission within 105 days from the date of this notice (105 days from December 6, 1991 for Project No. 11169).

Anyone may obtain an extension of time for these deadlines from the Commission only upon a showing of good cause or extraordinary circumstances in accordance with 18 CFR 385.2008.

All filings must (1) bear in all capital letters the title "PROTEST", "MOTION TO INTERVENE", "NOTICE OF INTENT TO FILE COMPETING APPLICATION," "COMPETING APPLICATION," "COMMENTS," "REPLY COMMENTS," "RECOMMENDATIONS," "TERMS AND CONDITIONS," or "PRESCRIPTIONS;" (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervenings; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, recommendations, terms and conditions or prescriptions must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). Agencies may obtain copies of the application directly from the applicant. Any of these documents must be filed by providing the original and the number of copies required by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426. An additional copy must be sent to Director, Division of Project Review, Office of Hydropower Licensing, Federal Energy Regulatory Commission, room 1027, at the above address. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

D8. Filing and Service of Responsive Documents—The application is not ready for environmental analysis at this time; therefore, the Commission is not now requesting comments, recommendations, terms and conditions, or prescriptions.

When the application is ready for environmental analysis, the Commission will issue a public notice requesting comments, recommendations, terms and conditions, or prescriptions.

All flings must (1) bear in all capital letters the title "PROTEST" or "MOTION TO INTERVENE," "NOTICE OF INTENT TO FILE COMPETING APPLICATION," or "COMPETING APPLICATION;" (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. Agencies may obtain copies of the application directly from the applicant. Any of these documents must be filed by providing the original and the number of copies required by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426. An additional copy must be sent to Director, Division of Project Review, Office of Hydropower Licensing, Federal Energy Regulatory Commission, room 1027, at the above address. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application.

D9. Filing and Service of Responsive Documents—The application is ready for environmental analysis at this time, and the Commission is requesting comments, reply comments, recommendations, terms and conditions, and prescriptions.

The Commission directs, pursuant to § 4.34(b) of the regulations (see Order No. 533 issued May 8, 1991, 56 FR 23108, May 20, 1991) that all comments, recommendations, terms and conditions and prescriptions concerning the application be filed with the Commission within 60 days from the issuance date of this notice (60 days from December 6, 1991 for Project No. 11128 and 60 days from November 26, 1991 for Project No. 11151). All reply comments must be filed with the Commission within 105 days from the date of this notice (105 days from December 6, 1991 for Project No. 11128 and 105 days from November 26, 1991 for Project No. 11151).

Anyone may obtain an extension of time for these deadlines from the Commission only upon a showing of good cause or extraordinary circumstances in accordance with 18 CFR 385.2008.

All filings must (1) bear in all capital letters the title "COMMENTS", "REPLY COMMENTS", "RECOMMENDATIONS," "TERMS AND CONDITIONS," or "PRESCRIPTIONS;" (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person submitting the filing; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, recommendations, terms and conditions or prescriptions must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). Any of these documents must be filed by providing the original and the number of copies required by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, DC 20426. An additional copy must be

sent to Director, Division of Project Review, Office of Hydropower Licensing, Federal Energy Regulatory Commission, room 1027, at the above address. Each filing must be accompanied by proof of service on all persons listed on the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b), and 385.2010.

E. Filing and Service of Responsive Documents—The application is not ready for environmental analysis at this time; therefore, the Commission is not now requesting comments, recommendations, terms and conditions, or prescriptions.

When the application is ready for environmental analysis, the Commission will issue a public notice requesting comments, recommendations, terms and conditions, or prescriptions.

All filings must (1) bear in all capital letters the title "PROTEST" or "MOTION TO INTERVENE;" (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. Any of these documents must be filed by providing the original and the number of copies required by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, DC 20426. An additional copy must be sent to Director, Division of Project Review, Office of Hydropower Licensing, Federal Energy Regulatory Commission, room 1027, at the above address. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application.

Dated: December 17, 1991, Washington, DC.

Lois D. Cashell,

Secretary.

[FR Doc. 91–30619 Filed 12–23–91; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. ES92–22–000]

Cambridge Electric Light Co.; Application

December 18, 1991.

Take notice that on December 13, 1991, Cambridge Electric Light Company filed an application with the Federal Energy Regulatory Commission under section 204 of the Federal Power Act requesting authority to issue not more than $25 million of short-term debt on or before December 31, 1993, with a final maturity date no later than December 31, 1994.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426 in accordance with rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before December 27, 1991. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 91–30626 Filed 12–23–91; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. ER92–97–000]

Central Louisiana Electric Co., Inc.; Filing

December 18, 1991.

Take notice that on November 15, 1991, Central Louisiana Electric Company (CLECO) tendered for filing supplemental cost support information to its October 7, 1991 filing.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 18 CFR 385.214). All such motions or protests should be filed on or before December 31, 1991. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 91–30624 Filed 12–23–91; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP90–143–009]

CNG Transmission Corp., Proposed Changes in FERC Gas Tariff

December 18, 1991.

Take notice that CNG Transmission Corporation ("CNG"), on December 13, 1991, pursuant to section 4 of the Natural Gas Act and part 154 of the Commission's regulations, filed tariff sheets to comply with the Commission's November 29, 1991 order in this proceeding.

CNG states that the purpose of its filing is to implement volumetric transportation and storage rate reductions equivalent to its previously filed sales commodity rate reductions in this proceeding, as required by the Commission. The proposed effective dates are December 1, 1991, and January 1, 1992.

CNG states that it has provided copies of its filing to its customers and interested state commissions.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with rule 211 of the Commission's Rules of Practice and Procedure 18 CFR 385.211. All such protests should be filed on or before December 26, 1991. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Louis D. Cashell,

Secretary.

[FR Doc. 91–30623 Filed 12–23–91; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. ES92–21–000]

Commonwealth Electric Co.; Application

December 18, 1991.

Take notice that on December 13, 1991, Commonwealth Electric Company filed an application with the Federal Energy Regulatory Commission under section 204 of the Federal Power Act requesting authority to issue not more than $100 million of short-term debt on or before December 31, 1993, with a final maturity date no later than December 31, 1994.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington,

DC 20426 in accordance with rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before December 27, 1991. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 91-30625 Filed 12-23-91; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP92-16-001]

El Paso Natural Gas Co.; Compliance Filing

December 18, 1991.

Take notice that on December 12, 1991, El Paso Natural Gas Company ("El Paso") tendered for filing with the Federal Energy Regulatory Commission ("Commission") certain tariff sheets to be included in its FERC Gas Tariff, Second Revised Volume No. 1, in compliance with ordering paragraph (A) of the Commission's "Order Accepting Tariff Sheet Subject to Refund and Conditions," issued November 27, 1991 at Docket No. RP92-16-000.

El Paso states that on October 28, 1991, at Docket No. RP92-16-000, it filed Third Revised Sheet No. 100B, reflecting the confidential nature of the negotiated Gas Cost Inventory Charge and Gas Cost Ceiling Charge rates for Southwest Gas Corporation under El Paso's Rate Schedule GIC. Such rates were effective November 1, 1991 with El Paso requesting confidential treatment of the rates until December 1, 1991.

El Paso states that ordering paragraph (A) of the Commission's November 27, 1991 order, provided for acceptance of Third Revised Sheet No. 100B to be effective November 1, 1991, subject to El Paso filing within fifteen (15) days of the date of the order, revised, separately stated rates and tariff language as stated in the order. The Commission found that El Paso's request to keep its rates confidential from its competitors for a month was acceptable, but found that El Paso had not separately stated its gas and non-gas costs in its statement of actual rates to be charged as previously ordered. In addition, the Commission stated that the confidential treatment of the Gas Inventory Charge rate applies only to gas costs. El Paso was directed to state publicly the non-gas cost component of its rate in its tariff and under the headings "Gas Cost Ceiling Charge" and "Has Inventory Charge," to substitute the word "Negotiated" for "Confidential." Further, the Commission directed El Paso to amend its tariff to state that the gas cost component rate is filed with the Commission and may be inspected at the end of the applicable month, unless otherwise ordered pursuant to § 388.112 of the Commission's Regulations.

Accordingly, El Paso states that it is submitting tariff sheets which reflect the changes required by the Commission's November 27, 1991 order.

El Paso respectfully requests waiver of the Commission's Regulations, as appropriate, in order that tendered Substitute Third Revised Sheet No. 100B and First Revised Sheet No. 281 may become effective November 1, 1991 and tendered 1st Rev Fourth Revised Sheet No. 100B may become effective December 1, 1991.

El Paso states that copies of the filing were served upon all parties of record at Docket No. RP92-16-000 and interested state regulatory commissions.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with rule 211 of the Commission's Rules of Practice and Procedure 18 CFR 385.211. All such protests should be filed on or before December 26, 1991. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 91-30621 Filed 12-23-91; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP92-54-000]

North Penn Gas Co.; Petition for Limited Waiver of the Base Rate Restatement Requirement

December 18, 1991.

Take notice that on December 6, 1991, North Penn Gas Company (North Penn) filed a petition asking the Commission to waive the requirement (under 18 CFR 154.303(e)) that it file a base rate restatement by January 31, 1922.

North Penn represents that it is negotiating a settlement [1] that would allow it to provide all jurisdictional services under a blanket certificate at rates that would be derived from retail rates established by the Pennsylvania Public Utility Commission. Assuming the Commission approves the settlement, North Penn's rates would no longer be set by the Commission and North Penn would not have to file a base rate restatement. Accordingly, North Penn asks that the Commission waive this filing deadline, so that it not have to divert resources to prepare a restatement filing that will likely have no effect. North Penn asks the Commission to rule expeditiously on its petition, given that the restatement is due on January 31, 1992.

North Penn states that copies of the filing have been served upon its wholesale customers and the Pennsylvania Public Utility Commission.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with 18 CFR 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests should be filed on or before December 26, 1991. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the public reference room.

Lois D. Cashell,

Secretary.

[FR Doc. 91-30622 Filed 12-23-91; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP92-55-000]

Northwest Pipeline Corp.; Proposed Change in FERC Gas Tariff

December 18, 1991.

Take notice that on December 16, 1991, Northwest Pipeline Corporation ("Northwest") tendered for filing and acceptance Tenth Revised Sheet No. 13 to become a part of its FERC Gas Tariff, Second Revised Volume No. 1.

On December 16, 1991, Northwest filed its Annual Report and Cost-of-Service Study to establish a revised Facility Charge and an Amortizing

[1] In Docket Nos. RP91-111-000, CP91-2649-000, and SA91-8-000.

Adjustment relating to Rate Schedule T–1. The December 16 proposal was prepared in accordance with the provisions of Northwest's December 6, 1989 Amended Compliance Filing (RP88–47 *et al*) which was accepted by the Commission on December 19, 1989.

Northwest requests waiver of the Commission's regulations to permit an effective date of February 1, 1992. A copy of this filing is being mailed to all jurisdictional customers and affected state commissions.

Any person desiring to be heard or protest said filing should file a motion to intervene of protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with §§ 385.214 and 385.211 of the Commission's Rules of Practice and Procedure. All such motions or protests should be filed on or before December 26, 1991. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 91–30620 Filed 12–23–91; 8:45 am]

BILLING CODE 6717–01–M

Office of Fossil Energy

[FE Docket No. 91–100–NG]

Mobil Natural Gas Inc.; Application To Import Natural Gas, including LNG

AGENCY: Office of Fossil Energy, Department of Energy.

ACTION: Notice of application for blanket authorization to import natural gas, including LNG.

SUMMARY: The Office of Fossil Energy (FE) of the Department of Energy (DOE) gives notice of receipt on November 19, 1991, of an application filed by Mobil Natural Gas Inc. (MNGI) for blanket authorization to import up to 100 Bcf of natural gas, including liquified natural gas (LNG), over a two-year term beginning on the date of first delivery after February 15, 1991, the date MNGI's current blanket import authorization expires. MNGI intends to utilize existing pipeline and LNG facilities for the transportation of the volumes to be imported and would submit quarterly reports detailing each transaction.

The application is filed under section 3 of the Natural Gas Act and DOE Delegation Order Nos. 0204–111 and 0204–127. Protests, motions to intervene, notices of intervention, and written comments are invited.

DATES: Protests, motions to intervene or notices of intervention, as applicable, requests for additional procedures and written comments are to be filed at the address listed below no later than 4:30 p.m., eastern time, January 23, 1992.

ADDRESSES: Office of Fuels Programs, Fossil Energy, U.S. Department of Energy, Forrestal Building, room 3F–056, FE–50, 1000 Independence Avenue, SW., Washington, DC 20585.

FOR FURTHER INFORMATION CONTACT:

Allyson C. Reilly, Office of Fuels Programs, Fossil Energy, U.S. Department of Energy, Forrestal Building, room 3F–094, FE–53, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586–9394.

Lot Cooke, Office of Assistant General Counsel for Fossil Energy, U.S. Department of Energy, Forrestal Building, room 6E–042, GC–14, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586–0503.

SUPPLEMENTARY INFORMATION: MNGI is a Delaware corporation with its principal place of business in Houston, Texas. MNGI is a marketer of natural gas in the United States and Canada and a wholly owned subsidiary of Mobil Fairfax Inc. MNGI has an existing blanket import authorization, issued on February 16, 1990, in DOE Opinion and Order No. 385 (1 FE ¶ 70,305) which expires on February 15, 1992. MNGI is requesting that the applied for authorization be granted no later than the expiration date of its current authorization.

MNGI proposes to import natural gas and LNG under competitive spot and short-term arrangements based on market conditions. MNGI would import for its own account or as an agent for the account of others.

The decision on the application for import authority will be made consistent with the DOE's gas import policy guidelines, under which the competitiveness of an import arrangement in the markets served is the primary consideration in determining whether it is in the public interest (49 FR 6684, February 22, 1984). Parties, especially those that may oppose this application, should comment in their responses on the issue of competitiveness as set forth in the policy guidelines. The applicant asserts that imports made under this arrangement will be competitive. Parties opposing the arrangement bear the burden of overcoming this assertion.

NEPA Compliance

The National Environmental Policy Act (NEPA), 42 U.S.C. 4321 *et seq.*, requires DOE to give appropriate consideration to the environmental effects of its proposed actions. No final decision will be issued in this proceeding until DOE has met its NEPA responsibilities.

Public Comment Procedures

In response to this notice, any person may file a protest, motion to intervene or notice of intervention, as applicable, and written comments. Any person wishing to become a party to the proceeding and to have their written comments considered as the basis for any decision on the application must, however, file a motion to intervene or notice of intervention, as applicable. The filing of a protest with respect to this application will not serve to make the protestant a party to the proceeding, although protests and comments received from persons who are not parties will be considered in determining the appropriate action to be taken on the application. All protests, motions to intervene, notices of intervention, and written comments must meet the requirements that are specified by the regulations in 10 CFR part 590. Protests, motions to intervene, notices of intervention, requests for additional procedures, and written comments should be filed with the Office of Fuels Programs at the above address.

It is intended that a decisional record will be developed on the application through responses to this notice by parties, including the parties' written comments and replies thereto. Additional procedures will be used as necessary to achieve a complete understanding of the facts and issues. A party seeking intervention may request that additional procedures be provided, such as additional written comments, an oral presentation, a conference, or trial-type hearing. Any request to file additional written comments should explain why they are necessary. Any request for an oral presentation should identify the substantial question of fact, law, or policy at issue, show that it is material and relevant to a decision in the proceeding, and demonstrate why an oral presentation is needed. Any request for a conference should demonstrate why the conference would materially advance the proceeding. Any request for a trial-type hearing must show that there are factual issues genuinely in dispute that are relevant and material to a decision and that a trial-type hearing is

necessary for a full and true disclosure of the facts.

If an additional procedure is scheduled, notice will be provided to all parties. If no party requests additional procedures, a final opinion and order may be issued based on the official record, including the application and responses filed by parties pursuant to this notice, in accordance with 10 CFR 590.316.

A copy of MNGI's application is available for inspection and copying in the Office of Fuels Programs Docket Room, 3F-056, at the above address. The docket room is open between the hours of 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC, December 19, 1991.

Clifford P. Tomaszewski,

Acting Deputy Assistant Secretary for Fuels Programs, Office of Fossil Energy.

[FR Doc. 91-30707 Filed 12-23-91; 8:45 am]

BILLING CODE 6450-01-M

ENVIRONMENTAL PROTECTION AGENCY

[FRL-4086-8]

Agency Information Collection Activities Under OMB Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this notice announces that the Information Collection Request (ICR) abstracted below has been forwarded to the Office of Management and Budget (OMB) for review and comment. The ICR describes the nature of the information collection and its expected cost and burden; where appropriate, it includes the actual data collection instrument.

DATES: Comments must be submitted on or before January 23, 1992.

FOR FURTHER INFORMATION CONTACT: Sandy Farmer at EPA, (202) 260-2740.

SUPPLEMENTARY INFORMATION:

Office of Air and Radiation

Title: Survey of Wood Furniture Manufacturers for the Purpose of Developing a National Emissions Standard for Hazardous Air Pollutants (NESHAP) for the Wood Furniture Manufacturing Industry (EPA ICR #1607.01). This is a new information collection.

Abstract: This information collection is a one-time survey of manufacturers of wood furniture. Respondents will be selected by sampling within Standard Industrial Classification (SIC) codes 2434, 2511, 2512, 2517, 2519, 2521, 2531, and 2541. The survey requests information on the processes involved in manufacturing wood furniture, the sources and quantities of emissions of hazardous air pollutants (HAP's), and the technologies in use by the industry to control such emissions. EPA will use the data from this survey to establish the maximum achievable control technology (MACT) floor as required under section 112(d) of the Clean Air Act. The results from this survey will also be used to define subcategories for the industry. Thirty of the respondents will be asked to complete a more extensive survey which requests more detailed information on operating parameters and processes. EPA will use this information to define and develop model plants for the industry.

Burden Statement: The public reporting burden for this collection of information is estimated to average 16.2 hours per response. This estimate includes the time needed to review instructions, search existing data sources, gather the data needed and review the collection of information.

Respondents: Manufacturers of wood furniture.

Estimated Annual No. of Respondents: 894.

Estimated No. of Responses per Respondent: One.

Estimated Total Annual Burden: 14,483 hours.

Frequency of Collection: Once.

Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestions for reducing the burden, to:

Sandy Farmer, U.S. Environmental Protection Agency, Information Policy Branch (PM-223Y), 401 M Street, SW., Washington, DC 20460

and

Troy Hillier, Office of Management and Budget, Office of Information and Regulatory Affairs, 725 17th Street, NW., Washington, DC 20503.

Please include the ICR number in any correspondence.

Dated: December 18, 1991.

Paul Lapsley,

Director, Regulatory Management Division.

[FR Doc. 91-30691 Filed 12-23-91; 8:45 am]

BILLING CODE 6560-50-M

[FRL-4086-6]

Expert Panel Workshop

AGENCY: U.S. Environmental Protection Agency.

ACTION: Notice of workshop on potential hazards associated with municipal solid waste recycling.

SUMMARY: This notice announces the second expert panel workshop to be held by the Environmental Criteria and Assessment Office (ECAO-Cin) of EPA's Office of Health and Environmental Assessment. This workshop will focus on expert panel review of the workshop review draft report titled, Potential Hazards Associated with Municipal Solid Waste Recycling.

DATES: The workshop will be held on January 7, 1992, from 1 p.m. to 5 p.m. and January 8, 1992, from 8 a.m. to 4 p.m. at the Drawbridge Inn, I-75 and Buttermilk Pike, Fort Mitchell, Kentucky.

ADDRESSES: ILSI Risk Science Institute under a Cooperative Agreement with EPA is providing logistical support and cochairing the workshop. Members of the public are invited to attend as observers. Seating is restricted. Individuals wishing to attend are urged to contact Diane Dalisera, 1126 Sixteenth Street, NW., Washington, DC 20036; Telephone (202) 659-3306. The workshop review draft will be available for public inspection at the workshop, and observers will have an opportunity to make brief comments at the end of each day.

FOR FURTHER INFORMATION CONTACT: Eletha Brady-Roberts, U.S. Environmental Protection Agency, Office of Health and Environmental Assessment, Environmental Criteria and Assessment Office (MS-190), Cincinnati, Ohio 45268; telephone (513) 569-7662 or (FTS) 684-7662.

SUPPLEMENTARY INFORMATION: Emissions from Municipal solid waste (MSW) recycling have become a matter of great public interest. However, the potential adverse effects on human health and the environment are as yet unexplored. The purpose of this project is to develop a document that describes the potential hazards of MSW recycling practices and to make this information available to solid waste managers in a form that will assist them in making decisions.

The MSW components that are highlighted in this document are as follows: Aluminum, bi-metal cans (steel/tin), glass, paper, and plastics (HDPE, PET, and PVC). A general overview of recycling practices (collection, sorting, and transportation) and the hazards associated with each practice will be included. A more detailed discussion of recycling technologies for each component and the potential hazards

associated with the processes will be provided.

Dated: December 12, 1991.

Erich Bretthauer,

Assistant Administrator for Research and Development.

[FR Doc. 91-30693 Filed 12-23-91; 8:45 am]

BILLING CODE 6560-50-M

[OPP-42068; FRL-3940-8]

Missouri Plan for Certification of Commercial and Private Applicators of Restricted Use Pesticides

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of intent to approve amendments to the Missouri State Plan.

SUMMARY: The State of Missouri has submitted to EPA proposed amendments to the Missouri State Plan for Certifying Pesticide Applicators. Missouri is proposing the amendments to bring the Plan in line with their amended Missouri Pesticide Use Act which became effective on January 1, 1990, and their amended Rules which became effective on January 1, 1990 and July 1, 1990. Proposed amendments to the Plan include, but are not limited to, establishment of a pesticide technician license, authority to assess civil penalties against individuals violating the Act, establishment of a passing score for an examination, and expansion of applicator and dealer recordkeeping requirements.

DATES: Written comments must be submitted on or before January 23, 1992.

ADDRESSES: Address comments identified by the docket control number OPP-42068 to David A. Ramsey, Toxics and Pesticides Branch, Air and Toxic Substances Division, Region VII, U. S. Environmental Protection Agency, 726 Minnesota Avenue, Kansas City, KS 66101.

Copies of the proposed amended plan are available for review at the following locations during normal business hours:

1. Division of Plant Industries, Missouri Department of Agriculture, 1616 Missouri Boulevard, Jefferson City, MO 65101.
2. Toxics and Pesticides Branch, U. S. Environmental Protection Agency, Region VII, 726 Minnesota Avenue, Kansas City, KS 66101.
3. Field Operations Division (H7506C), Office of Pesticide Programs, rm. 1128, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, Telephone: (703) 308-5805.

FOR FURTHER INFORMATION CONTACT: David Ramsey (314) 636-5223.

SUPPLEMENTARY INFORMATION: In accordance with the provisions of section 11(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, U. S. C. 136(b) and 40 CFR part 171, Missouri has requested EPA approval of amendments to their Certification Plan for Applicators of Restricted Use Pesticides. The Plan was originally approved by EPA on January 13, 1978.

Missouri is proposing establishment of a pesticide technician license for persons working under the direct supervision of commercial applicators in the category of Ornamental and Turf Pest Control and subcategories of General Structural Pest Control and Termite Pest Control. Applicants for a pesticide technician license must have successfully completed verifiable training approved by the director of the department of agriculture.

Missouri is proposing the establishment of a civil penalty authority over individuals violating provisions of the Missouri Pesticide Use Act and regulations issued thereunder. The director will have the authority to assess a civil penalty for each violation and, in addition, may order that restitution be made to any person.

Missouri is proposing a passing score of 70 percent on each examination required for certification of commercial applicators, noncommercial applicators, and public operators.

Lastly, Missouri is proposing the expansion of pesticide applicator and dealer recordkeeping requirements. Certified commercial applicators shall be required to maintain records for the use of any pesticide.

Dated: November 27, 1991.

William Rice,

Acting Regional Administrator, Region VII.

[FR Doc. 91-30325 Filed 12-23-91; 8:45 am]

BILLING CODE 6560-50-F

[PF-556; FRL-4006-1]

DowElanco; Notice of Filing of Food Additive Petition for Chlorpyrifos

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received from DowElanco a food additive petition (FAP 6H5505) requesting the establishment of a tolerance for residues of the insecticide chlorpyrifos, per se, in or on all food items (other than those already covered by a higher tolerance as a result of use on growing crops) in food service establishments where food and food products are prepared and served, as a result of the application of chlorpyrifos in microencapsulated form as a crack and crevice or spot treatment.

ADDRESSES: By mail, submit written comments identified by the document control number, [PF-556], to: Public Response and Program Resources Branch, Field Operations Division (H7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to: Rm. 1128, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Information submitted and any comment(s) concerning this notice may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment(s) that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice to the submitter. Information on the proposed test and any written comments will be available for public inspection in Rm. 1128 at the Virginia address given above, from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Dennis H. Edwards, Jr., Product Manager (PM-19), Registration Division (H-7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 207, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703)-305-6386.

SUPPLEMENTARY INFORMATION: This notice announces that EPA has received from DowElanco, P.O. Box 1706, Midland, MI, a food additive petition (FAP 6H5505) proposing to amend 40 CFR 185.1000 by establishing a food additive regulation for the microencapsulated form of the insecticide chlorpyrifos [O,O-diethyl O-(3,5,6-trichloro-2-pyridyl) phosphorothioate]. The petitioner subsequently amended the petition by proposing a tolerance of 0.1 part per million (ppm) for residues of chlorpyrifos, per se, in or on all food items (other than those already covered by a higher tolerance as a result of use on growing crops) in food service establishments when food and food products are prepared and served.

Authority: 21 U.S.C. 346a and 348.

Dated: December 16, 1991.

Anne E. Lindsay,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 91–30771 Filed 12–23–91; 8:45 am]

BILLING CODE 6560–50–F

FEDERAL COMMUNICATIONS COMMISSION

Public Information Collection Requirement Submitted to Office of Management and Budget for Review

The Federal Communications Commission has submitted the following information collection requirement to OMB for review and clearance under the Paperwork Reduction Act of 1980 (44 U.S.C. 3507).

Copies of this submission may be purchased from the Commission's copy contractor, Downtown Copy Center, 1114 21st Street, NW., Washington, DC 20036, (202) 452–1422. For further information on this submission contact Judy Boley, Federal Communications Commission, (202) 632–7513. Persons wishing to comment on this information collection should contact Jonas Neihardt, Office of Management and Budget, room 3235 NEOB, Washington, DC 20503, (202) 395–4814.

OMB Number: 3060–0003.
Title: Application for Amateur Radio Station and Operator License.
Form Number: FCC Form 610.
Action: Revision.
Respondents: Individuals or households.
Frequency of Response: On occasion reporting.
Estimated Annual Burden: 95,050 responses; .166 hours average burden per response; 15,778 hours total annual burden.
Needs and Uses: The FCC Form 610 is used to apply for a new, renewal, or modified amateur radio station and operator license. The revision to this information collection consists of minor changes on the form including instructions for physicians who certify that an individual is unable to pass a telegraphy examination. Commission personnel use the data to determine eligibility for a radio station authorization and to issue a radio station/operator license. Data is also used by Compliance personnel in conjunction with Field Engineers for enforcement and interference purposes.

Federal Communications Commission.

Donna R. Searcy,

Secretary.

[FR Doc. 91–30643 Filed 12–23–91; 8:45 am]

BILLING CODE 6712–01–M

FEDERAL MARITIME COMMISSION

[Docket No. 91–60]

Southern Steam, Inc., as Agent for Wallenius Transroll v. Consolidated American Group; Filing of Complaint and Assignment

Notice is given that a complaint filed by Southern Steam Incorporated ("Complainant") against Consolidated American Group ("Respondent") was served December 18, 1991. Complainant alleges that Respondent engaged in violations of section 10(a)(1) of the Shipping Act of 1984, 46 U.S.C. app. 1709(a)(1), by failing to pay the ocean freight on a shipment of synthetic staple fiber between Norfolk, Virginia and Sao Paulo, Brazil.

This proceeding has been assigned to Administrative Law Judge Charles E. Morgan ("Presiding Officer"). Hearing in this matter, if any is held, shall commence within the time limitations prescribed in 46 CFR 502.61. The hearing shall include oral testimony and cross-examination in the discretion of the Presiding Officer only upon proper showing that there are genuine issues of material fact that cannot be resolved on the basis of sworn statements, affidavits, depositions, or other documents or that the nature of the matter in issue is such that an oral hearing and cross-examination are necessary for the development of an adequate record. Pursuant to the further terms of 46 CFR 502.61, the initial decision of the Presiding Officer in this proceeding shall be issued by December 18, 1992, and the final decision of the Commission shall be issued by April 19, 1993.

Joseph C. Polking,

Secretary.

[FR Doc. 91–30632 Filed 12–23–91; 8:45 am]

BILLING CODE 6730–01–M

FEDERAL TRADE COMMISSION

[Dkt 9216]

Hoechst Celanese Corporation, et al.; Prohibited Trade Practices, and Affirmative Corrective Actions

AGENCY: Federal Trade Commission.

ACTION: Consent Order.

SUMMARY: In settlement of alleged violations of federal law prohibiting unfair acts and practices and unfair methods of competition, this consent order prohibits, among other things, a German company and its U.S. subsidiaries, for a period of ten years from entering into any agreement, with any producer of acetal products, to allocate, divide or restrict competition in markets for acetal products. In addition, the consent order prohibits the respondents from using certain restrictions to limit competition from Daicel Chemical Industries and Polyplastics Company of Japan, their partners in a joint venture.

DATES: Complaint issued November 17, 1988. Order issued November 26, 1991.[1]

FOR FURTHER INFORMATION CONTACT: Rhett Krulla, FTC/S–3302, Washington, DC 20580. (202) 326–2608.

SUPPLEMENTARY INFORMATION: On Wednesday, September 4, 1991, there was published in the **Federal Register**, 56 FR 43771, a proposed consent agreement with analysis In the Matter of Hoechst Celanese Corporation, et al., for the purpose of soliciting public comment. Interested parties were given sixty (60) days in which to submit comments, suggestions or objections regarding the proposed form of the order.

No comments having been received, the Commission has ordered the issuance of the complaint in the form contemplated by the agreement, made its jurisdictional findings and entered an order to cease and desist, as set forth in the proposed consent agreement, in disposition of this proceeding.

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interpret or apply sec. 5, 38 Stat. 719, as amended; sec. 7, 38 Stat. 731, as amended; 15 U.S.C. 45, 18)

Donald S. Clark,

Secretary.

[FR Doc. 91–30689 Filed 12–23–91; 8:45 am]

BILLING CODE 6750–01–M

[Dk. 9200]

Removatron International Corporation, et al.; Prohibited Trade Practice and Affirmative Corrective Actions

AGENCY: Federal Trade Commission.

ACTION: Modifying Order.

SUMMARY: This order reopens the proceeding and modifies the Commission's 1988 final order—requiring respondents to cease making certain claims about their hair-removal device—by setting aside a provision requiring an affirmative disclosure in conjunction with certain efficacy claims. However, the respondents are still prohibited by the order from making unsubstantiated hair-removal claims.

[1] Copies of the Complaint and the Decision and Order are available from the Commission's Public Reference Branch, H–130, 6th Street, & Pennsylvania Avenue, NW., Washington, DC 20580.

DATES: Final order issued November 4, 1988. Modifying order issued November 20, 1991.

FOR FURTHER INFORMATION CONTACT: Thomas Massie, FTC/S–4631, Washington, DC 20580. (202) 326–2982.

SUPPLEMENTARY INFORMATION: In the Matter of Removatron International Corporation, et al. The prohibited trade practices and/or corrective actions as set forth at 54 FR 1160, are set aside, in part, as noted in the order that follows.

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interprets or applies sec. 5, 38 Stat. 719, as amended; 15 U.S.C. 45, 52)

Order Reopening the Proceeding and Modifying Cease and Desist Order

On July 23, 1991, Removatron International Corporation and Frederick E. Goodman (Petitioners) filed a petition pursuant to section 5(b) of the Federal Trade Commission Act, 15 U.S.C. 45(b), and rules 2.51 and 3.72 of the Commission's Rules of Practice, 16 CFR 2.51 and 3.72, to reopen the proceeding and modify the final cease and desist order issued against them by the Commission on November 4, 1988, in Docket No. 9200 (111 F.T.C. 206), and upheld by the United States Court of Appeals for the First Circuit on September 11, 1989, in *Removatron International Corp.* v. *F.T.C.*, 884 F.2d 1489 (1st Cir. 1989).

The final order in this matter was the product of litigation concerning unsubstantiated claims of permanent or long-term (as opposed to temporary) hair removal for the Removatron radio frequency energy (RFE) tweezer-type apilation device. Part I.A of the order prohibits Petitioners from making permanent as long-term hair removal representations with respect to their RFE epilator unless they possess and rely upon competent and reliable scientific evidence that substantiates such representation. The order defines competent and reliable scientific evidence as adequate and well-controlled, double-blind clinical testing conforming to acceptable designs and protocols and conducted by a person or persons qualified by training and experience to conduct such testing. Part I.B of the order prohibits Petitioners, for a period of five (5) years, from representing that their RFE epilator is intended to or is able to remove hair unless the following disclosure is also made:

Important: There is no reliable evidence that (name of device treatments) provides anything more than temporary hair removal.

The request to reopen the proceeding to set aside Part I.B of the order was filed on July 23, 1991. The request was placed on the public record for thirty days for the purpose of receiving public comment on July 29, 1991. No comments were received during the comment period.

Standard for Reopening a Final Order of the Commission

Section 5(b) of the Federal Trade Commission Act, 15 U.S.C. 45(b), provides that the Commission shall reopen an order to consider whether it should be altered, modified, or set aside if the respondent "makes a satisfactory showing that changed conditions of law or fact" so require.[1] A satisfactory showing sufficient to require reopening is made when a request to reopen identifies significant changes in circumstances and shows that the changes eliminate the need for the order or make continued application of the order inequitable or harmful to competition. *Louisiana Pacific Corp.*, Docket No. C–2956, Letter to John C. Hart (June 5, 1986) at 4. See, S. Rep. No. 96–500, 96th Cong., 2d Sess. 9 (1979) (significant change or changes causing unfair disadvantage); see *Phillips Petroleum Co.*, Docket No. C–1088, 78 F.T.C. 1573, 1575 (1971) (modification not required for changes reasonably foreseeable at time of consent applications); *Pay Less Drugstores Northwest, Inc.*, Docket No. C–3039, Letter to H.B. Hummelt (Jan. 22, 1982) (changed condition must be unforeseeable, create severe competitive hardship and eliminate dangers order sought to remedy) (unpublished); see also *United States* v. *Swift & Co.*, 286 U.S. 106, 119 (1932) ("clear showing" of changes that eliminate reasons for order or such that order causes unanticipated hardship).

The language of section 5(b) plainly anticipates that the burden is on the requester to make "a satisfactory showing" of changed conditions to obtain reopening of the order. *See also Gautreaux* v. *Pierce*, 535 F. Supp. 423, 426 (N.D. Ill. 1982) (requester must show "exceptional circumstances, new, changed or unforeseen at the time the decree was entered"). The legislative history also makes clear that the requester has the burden of showing, by means other than conclusory statements, why an order should be modified.[2] If the Commission determines that the requester has made the necessary showing, the Commission must reopen the order to determine whether the modification is required and, if so, the nature and extent of the modification. The Commission is not required to reopen the order, however, if the requester fails to meet its burden of making the satisfactory showing of changed conditions required by the statute. The requester's burden is not a light one in view of the public interest in repose and finality of the Commission orders. *See Federated Department Stores, Inc.* v. *Moitie*, 425 U.S. 394 (1981) (strong public interest considerations support repose and finality); *Bowman Transportation, Inc.* v. *Arkansas-Best Freight System, Inc.*, 419 U.S. 281, 296 (1974) ("sound basis for * * * (not reopening) except in the most extraordinary circumstances"); *RSR Corp.* v. *FTC*, 656 F.2d 718, 721–22 (D.C. Cir. 1981) (applying *Bowman Transportation* standard to FTC order).

Changed Conditions of Fact Warrant Reopening the Order

Petitioners have requested that the Commission reopen and modify the order because changed conditions of fact and the public interest require such action. For the reasons described below, changes of fact warrant reopening and modifying the order against Petitioners. Having reopened and modified the order on the basis of changes of fact, the Commission does not reach the issue of whether the public interest warrants reopening.

Petitioners rely on a clinical study entitled "Evaluation of the Effect of Radio-Frequency Energy Delivered by the Removatron Hair Removal Device on Hair Regrowth" to support their request that Part I.B of the order be set aside. The study was conducted by Nellie Konnikov, M.D., Assistant Professor of Dermatology, Tufts

[1] Section 5(b) provides, in part:

[T]he Commission shall reopen any such order to consider whether such order (including any affirmative relief provision contained in such order) should be altered, modified, or set aside, in whole or in part, if the person, partnership, or corporation involved files a request with the Commission which makes a satisfactory showing that changed conditions of law or fact require such order to be altered, modified, or set aside, in whole or in part.

The 1980 amendment to Section 5(b) did not change the standard for order reopening and modification, but "codifie[d] existing Commission procedures by requiring the Commission to reopen an order if the specified showing is made," S. Rep. 96–500, 96th Cong., 2d Sess. 9–10 (1979), and added the requirement that the Commission act on petitions to reopen within 120 days of filing.

[2] The legislative history of amended section 5(b), S. Rep. No. 96–500, 96th Cong., 2d Sess. 9–10 (1979), states:

Unmeritorious, time-consuming and dilatory requests are not to be condoned. A mere facial demonstration of changed facts or circumstances is not sufficient . . . The Commission, to reemphasize, may properly decline to reopen an order if a request is merely conclusory or otherwise fails to set forth specific facts demonstrating in detail the nature of the changed conditions and the reasons why these changed conditions require the requested modification of the order.

University School of Medicine; Chief, Dermatology Section, Boston VA Hospital; and Director, Dermatology Residency Program, Tufts-New England Medical Center. Dr. Konnikov concluded that Removatron's RFE device "appears to provide a safe, painless, and effective approach to the troublesome problem of unwanted hair." Dr. Konnikov bases this conclusion on her observation that contrary to the hair regrowth on the control sites, 46% of the facial hairs treated with the Removatron device could be considered with reasonable medical certainty to have been permanently removed.

Petitioners have also submitted the qualified opinion of a Medical Officer of the Food and Drug Administration's (FDA) Center for Devices and Radiological Health that the Konnikov study provides reasonable assurance of the efficacy of the Removatron RFE device. The Medical Officer, in a reference to the Standards for the Treatment of Permanent Hair Removal of the International Guild of Professional Electrologists, found that the range of effectiveness was in the minimum bracket of 40–50%—and the number of hairs studied per person was low. Consequently, he recommended that a statistical analysis of the study be conducted before the study could be pronounced and unqualified final determination that there is adequate evidence of safety and effectiveness of the Removatron device.[3]

Petitioners also had Dr. Eugene Van Scott, a dermatologist who testified as an expert on behalf of complaint counsel at the trial of this matter, review the Konnikov study. Dr. Van Scott stated that overall the study reported was designed quite well and the results appeared to be valid. However, he questioned whether the papilla was destroyed, the generally accepted definition of permanent hair removal.

Based on the foregoing, Petitioners argue that they have sufficient evidence on which to base representations of efficacy, i.e., that Removatron's RFE device permanently removes hair. We do not agree. Arguably, the Konnikov study provides some evidence of permanent hair removal but it is by no means dispositive of this key issue. Supporting opinions are qualified, including that additional evidence will be required to substantiate permanent removal claims.

[3] The FDA, to our knowledge, has never conducted this statistical study. The FDA did compare the Konnikov study to the Standards of the International Guild of Professional Electrologists and determined there was not substantial equivalence between the RFE device and electrolysis.

Dr. Van Scott's review of the Konnikov study is especially instructive. First, Dr. Scott proposes three possible effects of RFE on the hair follicles' ability to grow hair, only one of which suggests the irreparable destruction of the papilla, the accepted definition of permanent removal. A second hypothesis is that the Removatron device merely extends the resting phase of the hair's growth period, the hair taking longer to grow back. A third hypothesis is that the Removatron device damages but does not destroy the papilla, causing the hair to grow back finer and shorter, so that it is no longer conspicuous but resembles the hair normally found in the affected region. The Konnikov study does not support the conclusion that permanent hair removal is the correct hypothesis among these three. Therefore, more study is needed.

Nevertheless, Dr. Van Scott has stated that he is convinced that RFE does something more than temporary hair removal. In his letter to the Petitioner Goodman, Dr. Van Scott wrote:

> In my judgment this study does a great deal to satisfy the earlier criticisms and reservations regarding the effects of RFE on hair. In this regard consideration should be given however to positioning the claims for RFE, that is, "permanent removal" versus "diminishment of hirsutism" or some such statement to indicate that conspicuous hairs are eradicated, or conspicuous hairs fail to regrow. To insist on "permanent removal" invites the controversy over permanent destruction. In fact, if RFE can restore follicles to a state of normalcy (for the skin region involved) that is, convert follicles from producing coarse, long hairs to follicles producing short, fine hairs—which is suggested by the study of Dr. Konnikov—this would be cosmetically more desirable than trying to achieve baldness for the region. The result would be to normalize hair for that region.

Dr. Van Scott believes the study is evidence that something more profound than temporary hair removal is occurring.

Part I.B of the Order Should Be Set Aside

Although the evidence presented is insufficient to substantiate a permanent removal representation, Part I.B does not require the same level of evidence to demonstrate a changed condition of fact. Since the evidence now demonstrates that Removatron's RFE epilation device achieves something more than temporary hair removal, Petitioners have shown that there is no need now for Part I.B of the order and that its continued application would be inequitable or harmful to competition.

It is Therefore Ordered That the proceeding is hereby reopened and that Part I.B of the final order effective November 10, 1989, in Docket No. 9200 is hereby set aside.

By the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 91–30690 Filed 12–23–91; 8:45 am]

BILLING CODE 6750–01–M

GENERAL SERVICES ADMINISTRATION

[GSAR Notice 5–324]

General Services Administration Acquisition Regulation; Revised GSA Forms 3504 and 3507

AGENCY: Office of Acquisition Policy, GSA.

ACTION: Notice.

SUMMARY: Notice is hereby given that GSAR Change 32 revised and illustrated the October 1991 editions of GSA Form 3504, Service Contract Clauses and GSA Form 3507, Supply Contract Clauses. Copies of the forms may be obtained from the Director of the Office of GSA Acquisition Policy (VP), 18th & F Sts., NW, Washington, DC 20405.

FOR FURTHER INFORMATION CONTACT: John Joyner, Office of GSA Acquisition Policy (202) 501–1224.

Dated: December 16, 1991.

Richard H. Hopf, III,

Associate Administrator for Acquisition Policy.

[FR Doc. 91–30649 Filed 12–23–91; 8:45 am]

BILLING CODE 6820–61–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Alcohol, Drug Abuse, and Mental Health Administration

Technical Assistance Workshops in February, March, April and May, 1992

OFFICE: Office for Treatment Improvement.

ACTION: Notice of generic technical assistance workshops.

SUMMARY: This notice sets forth the schedule and proposed agenda for the forthcoming five (5) regional technical assistance workshops to assist prospective applicants in responding to future grant announcements from the Office for Treatment Improvement (OTI). Generic technical assistance will be offered to prospective applicants.

The proposed schedule for the workshops is contingent on the level of interest expressed by potential attendees through pre-registration.

Region/Date/Location

Public Health Service Region IX, San Francisco, CA, February 13–14, 1992
Sir Frances Drake Hotel on Union Square, 450 Powell Street, San Francisco, CA 94102, (415) 392–7755
Public Health Service Region IV, Atlanta, GA, March 25–26, 1992
The Atlanta Hilton and Towers, 255 Courtland Street, Atlanta, GA 30303, (404) 659–2000
Public Health Service Region VIII, Denver, CO April 9–10, 1992
The Westin Hotel Tabor Center, 1672 Lawrence Street, Denver, CO 80202, (303) 572–9100
Public Health Service Region III, Washington, DC, April 30–May 1, 1992
Omni Shoreham Hotel, 2500 Calvert Street, NW., Washington, DC 20008, (202) 234–0700
Public Health Service Region V, Chicago, IL, May 14–15, 1992
The Palmer House, 17 East Monroe Street, Chicago, IL 60603, (312) 726–7500

Time

Day 1—Pre-registration and small group orientation will be held 6 to 8 p.m. OTI staff and reviewer participants will be available for informal discussions.

Day 2—The workshops will begin at 8:30 a.m. and adjourn at 5 p.m.

Agenda Highlights include:

Strategies for Successful Grant Submission and General Principles of the Review and Award Process
Technical/Practical Aspects of the Grant Application Process including: completing forms, program narrative, budget justification, management and evaluation
OTI Reviewer Participant Panel
Mock Review Panel
Questions and Answers

Status of Workshops: Open to prospective OTI grant applicants.

For further details including pre-registration information contact: Technical Resources, Incorporated, 3202 Tower Oaks Blvd., Rockville, Maryland 20852, (301) 770–7658.

Purpose

The Office for Treatment Improvement, Division of Review will sponsor general assistance workshops for perspective applicants responding to future OTI grant announcements.

Joseph R. Leone,

Associate Administrator for Management, Alcohol, Drug Abuse, and Mental Health Administration.

[FR Doc. 91–30715–Filed 12–23–91; 8:45 am]

BILLING CODE 4160–20–M

Centers for Disease Control

Advisory Committee for Injury Prevention and Control: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control (CDC), announces the following committee meeting:

Name: Advisory Committee for Injury Prevention and Control (ACIPC).

Time and Date: 8 a.m.–5 p.m., February 3, 1992, 8 a.m.–12 noon, February 4, 1992.

Place: Centers for Disease Control, Auditorium A, 1600 Clifton Road, NE, Atlanta, Georgia 30333.

Status: Open to the public, limited only by the space available.

Purpose: The Committee will continue to make recommendations on policy, strategy, objectives, and priorities including the balance and mix of intramural and extramural research; advise on the development of a national plan for injury prevention and control, the development of new technologies and their application; and review progress toward injury prevention and control.

Matters to be Discussed: The Committee will discuss building the field of injury control, progress in developing a national agenda for injury control, accomplishments of the CDC injury control program, community guidelines for the prevention of youth violence, tracking injury control objectives for the Year 2000, an update of the external cause of injury coding of hospital discharges, extramural research grants, and state based surveillance and intervention programs.

Agenda items are subject to change as priorities dictate.

CONTACT PERSON FOR MORE INFORMATION: John F. Finklea, M.D., Executive Secretary, ACIPC, Division of Injury Control, National Center for Environmental Health and Injury Control, CDC, 1600 Clifton Road, NE, Mailstop F–36, Atlanta, Georgia 30333, telephone 404/488–4690 or FTS 236–4690.

Dated: December 18, 1991.

Elvin Hilyer,

Associate Director for Policy Coordination, Centers for Disease Control.

[FR Doc. 91–30634 Filed 12–23–91; 8:45 am]

BILLING CODE 4160–18–M

Food and Drug Administration

[Docket No. 91N–0473]

AG-Mark, Inc., and Quali-Tech, Inc.; Withdrawal of Approval of NADA's

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of two animal drug applications (NADA's) held by Ag-Mark, Inc., and Quali-Tech, Inc. The NADA's provide for the manufacture of Type B medicated feeds containing lincomycin. The firms requested withdrawal of approval of the NADA's because an NADA is no longer required to manufacture or distribute the Type B medicated feed. In a final rule published elsewhere in this issue of the **Federal Register**, FDA is amending the regulations by removing and reserving the portions of the regulation that reflect approval of the NADA's.

DATES: January 3, 1992.

FOR FURTHER INFORMATION CONTACT: Mohammad I. Sharar, Center for Veterinary Medicine (HFV–216), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 301–295–8749.

SUPPLEMENTARY INFORMATION: Ag-Mark, Inc., P.O. Box 127, Teachey, NC 28464 and Quali-Tech, Inc., 318 Lake Hazeltine Dr., Chaska, MN 55318–1093, are the sponsors of NADA's 133–035 and 132–925, respectively. The firms requested the withdrawal of approval of the NADA's because an NADA is no longer required to manufacture or distribute the Type B medicated feed (See 51 FR 7382, March 3, 1986, and 55 FR 23423, June 8, 1990).

Therefore, under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Veterinary Medicine (21 CFR part 5.84), and in accordance with § 514.115 Withdrawal of approval of applications (21 CFR 514.115), notice is given that approval of NADA's 133–035 and 132–925 and all supplements and amendments thereto is hereby withdrawn, effective January 3, 1992.

In a final rule published elsewhere in this issue of the **Federal Register**, FDA is amending 21 CFR 558.325 by removing and reserving paragraphs (a)(8) and (a)(14) to reflect the withdrawal of the approval.

Dated: December 17, 1991.

Gerald B. Guest,

Director, Center for Veterinary Medicine.

[FR Doc. 91-30718 Filed 12-23-91; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WO-340-02-4333-02]

Information Collection Submitted to the Office of Management and Budget for Review Under the Paperwork Reduction Act

The proposal for the collection of information listed below has been submitted to the Office of Management and Budget for approval under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35). copies of the proposed collection of information and related forms may be obtained by contacting the Bureau's Clearance Officer at the phone number listed below. Comments and suggestions on the proposal should be directed to the Bureau Clearance Officer and to the Office of Management and Budget Interior Department Desk Officer, Washington, DC 20503, telephone (202) 395-7340.

Title: Access to Confidential Cave Data.
OMB approval number: Not yet assigned.
Abstract: Respondents supply information relating to requests for confidential cave data. This information is used to decide whether to grant access to this data as required under section 5 of the Federal Cave Resources Protection Act of 1988.
Bureau form number: None.
Frequency: Information relating to access to confidential cave data is submitted from the requesting organization as they identify need for the data.
Descriptionof respondents: Federal and State governmental agencies and their cooperators, and bona fide educational and research institutions.
Estimated completion time: One-half hour.
Annual responses: 200.
Annual burden hours: 100.
Bureau Clearance Officer (Alternate): Gerri Jenkins, 202-653-6105.

Dated: December 4, 1991.

Kemp Conn,

Acting Assistant Director—Land and Renewable Resources.

[FR Doc. 91-30652 Filed 12-23-91; 8:45 am]

BILLING CODE 4310-84-M

[WO-340-02-4333-02]

Information Collection Submitted to the Office of Management and Budget for Review Under the Paperwork Reduction Act

The proposal for the collection of information listed below has been submitted to the Office of Management and Budget for approval under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35). Copies of the proposed collection of information and related forms may be obtained by contacting the Bureau's Clearance Officer at the phone number listed below. Comments and suggestions on the proposal should be directed to the Bureau Clearance Officer and to the Office of Management and Budget Interior Department Desk Officer, Washington, DC 20503, telephone (202) 395-7340.

Title: Nomination of Significant Caves.
OMB approval number: Not yet assigned.
Abstract: Respondents supply information on caves on Federal lands. This information is used to help determine which caves will be listed as significant as required under section 4 of the Federal Cave Resources Protection Act of 1988.
Bureau form number: None.
Frequency: Information for the nomination of significant caves is collected on a one-time basis for each cave.
Description of respondents: Individuals or organizations that are interested in the protection of cave resources located on Federal lands.
Estimated completion time: 3 hours.
Annual responses: 500.
Annual burden hours: 1500.
Bureau Clearance Officer (Alternate): Gerri Jenkins, 202-653-6105.

Dated: December 4, 1991.

Kemp Conn,

Acting Assistant Director—Land and Renewable Resources.

[FR Doc. 91-30653 Filed 12-23-91; 8:45 am]

BILLING CODE 4310-84-M

[ES-020-02-4112-16]

Intent To Prepare an Environmental Assessment; Proposed Oil Well Site, Broward County, FL

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of intent to prepare an Environmental Assessment (EA) on a proposed oil well site in Broward County, Florida and notice of public meeting.

SUMMARY: Pursuant to the National Environmental Policy Act of 1969, the Bureau of Land Management (BLM), Jackson District and the Bureau of Indian Affairs (BIA), Eastern Area Office, as joint lead agencies, will be directing the preparation of an EA to be prepared by a third party contractor concerning a proposed oil well site on the Federal Miccosukee Indian Reservation in Broward County, Florida.

DATES: A public meeting will be held beginning at 5 p.m. on January 23, 1992 at the Fort Lauderdale Airport Hilton, 1870 Griffin Road, Dania, Florida. The meeting will be held to accept oral and written comments concerning the proposal. The comments will be used to identify issues and concerns considered in the preparation of the EA. Written comments will be accepted until February 14, 1992.

ADDRESSES: Comments should be sent to the District Manager, Bureau of Land Management, 411 Briarwood Drive, suite 404, Jackson, Mississippi 39206; Attn: Sid Vogelpohl.

FOR FURTHER INFORMATION CONTACT: Sid Vogelpohl (BLM) (601) 977-5400 or Jim Harriman (BIA) (703) 235-3177.

SUPPLEMENTARY INFORMATION:

1. Proposed Action.

On January 17, 1991, Shell Western E&P, Inc. (SWEPI) submitted an "Application for Permit to Drill" an exploratory well to the Bureau of Land Management. The proposed well is on the Miccosukee Indian Reservation in Broward County, Florida. The well is identified as the SWEPI Miccosukee 3-1 The site is located directly north of Interstate 75 and west of the L-28 Canal adjacent to Water Conservation Area 3A. The proposed site is on grasslands currently used for cattle grazing. The well is proposed to be drilled to a depth of 18,800 feet and would be a directional well with the bottom hole location approximately 4,600 feet east of the surface site. The location of the bottom hole would be underneath that portion of Water Conservation Area 3A located within the boundary of the Miccosukee Indian Reservation.

The drill site would be approximately square and utilize about five acres. A four-foot high berm, constructed of fill and topped with lime rock, would encompass the entire location. The proposed access road would start from a point approximately four miles north of I-75 off the Snake Road. The road would run east approximately two miles on an existing field road and then south approximately four miles on an existing field road and then south approximately

four miles on an existing road adjacent to and immediately west of the L-28 Canal.

2. Alternatives

It is anticipated that the alternatives will concentrate on evaluation of alternate drill sites and road routes with the objective of identifying the potential environmental impacts of alternatives, if any, relative to the proposed action. The alternatives must meet the criteria of being feasible in terms of environmental considerations as well as technological and geological considerations.

3. Public Participation

The public was invited on March 22, 1991 to identify issues and concerns which are specifically related to the proposed drilling activity. This public comment period ended on May 3, 1991. All comments previously provided have been maintained and do not need to be resubmitted.

Agencies and the public are also invited and encouraged to provide oral and/or written comments at the public meeting. Comments should specifically describe environmental issues or concerns which the commenter believes the EA should address. Any additional written comments should be sent, by the date noted above, to the BLM District Manager at the address noted above.

4. Availability of the EA

The time of completion of the EA is estimated to be October 1992.

Dated: December 17, 1991.

Donald H. Sweep,

Jackson District Manager, BLM.

[FR Doc. 91-30657 Filed 12-23-91; 8:45 am]

BILLING CODE 4310-GJ-M

[CA-010-02-4212-13; CACA-28683]

Realty Action; Proposed Land Exchange in Madera, Mariposa, Merced, Monterey, Fresno, and San Benito Counties, CA

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of realty action; exchange of public and private lands in Madera, Mariposa, Merced, Monterey, Fresno, and San Benito Counties, California (CACA-28683).

SUMMARY: The following described public lands are being considered for exchange to CAL-BLMX, Inc., under section 206 of the Federal Land Policy Management Act of 1976 (43 U.S.C. 1716). Some parcels have been identified for exchange of the surface estate while other parcels are identified for exchange of both surface and mineral estate.

NOTE: Not all the land identified below will be included in the exchange. Some parcels may be deleted to eliminate possible conflicts that could arise during processing. Additional lands previously identified for exchange to CAL-BLMX, Inc. and published in the **Federal Register** on March 30, 1990 may also be included in the exchange. The final selection of properties will be made to achieve comparable values between the offered and selected lands.

SELECTED PUBLIC LANDS: The following parcels are identified for exchange of both surface and mineral estate:

Mount Diablo Meridian, California

T. 5S., R. 19E.,
Sec. 32; Portion SE ¼.
T. 5S., R. 20E.,
Sec. 26; N½SW¼, NW¼SE¼.
T. 6S., R. 18E.,
Sec. 36; N½NW¼, SW¼NW¼, NW¼SW¼.
T. 6S., R. 19E.,
Sec. 1; SE¼NW¼;
Sec. 5; Portion NE¼;
Sec. 6; Lots 2 & 3, SW¼NE¼, SE¼NW¼;
Sec. 7; SE¼NE¼;
Sec. 8; N½NW¼, SW¼NW¼.
T. 6S., R. 20 E.,
Sec. 27; Lots 17 & 18.
T. 6S., R. 21E.,
Sec. 29; Lots 7, 10, 15.
T. 7S., R. 21E.,
Sec. 5; SW¼NE¼;
Sec. 16; N½SE¼;
Sec. 31; Lots 14 & 15.
T. 7S., R. 22E.,
Sec. 19; Lot 5.
T. 8S., R. 18E.,
Sec. 34; Lots 4 & 5.
T. 8S., R. 20E.,
Sec. 2; NE¼SE¼.
T. 8S., R. 21 E.,
Sec. 12; E½, E½NW¼, NE¼SW¼;
Sec. 13; NE¼NE¼.
T. 8S., R. 22E.,
Sec. 7; Lot 1, NE¼NW¼;
Sec. 9; SW¼NW¼.
T. 9S., R. 19E.,
Sec. 20; NW¼NE¼.
T. 9S., R. 22E.,
Sec. 6; Lot 11.
T. 11S., R. 23E.,
Sec. 2; SW¼NE¼;
Sec. 3; NE¼SW¼.
T. 11S., R. 24E.,
Sec. 22; SW¼SE¼.
T. 12S., R. 23E.,
Sec. 15; E½SE¼;
Sec. 22; E½NE¼.
T. 12S., R. 24E.,
Sec. 22; NE¼SW¼.
T. 13S., R. 24E.,
Sec. 8; SE¼SE¼, Lots 17 & 18;
Sec. 9; SW¼SW¼;
Sec. 24; SW¼SE¼.
T. 13S., R. 25E.,
Sec. 10; NE¼SW¼;
Sec. 13; NE¼SW¼;
Sec. 24; N½SE¼, SW¼SE¼;
Sec. 25; W½NE¼, S½NW¼, NE¼SW¼, NW¼SE¼.
T. 13S., R. 26E.,
Sec. 7; W½NE¼;
Sec. 19; NE¼SW¼.

Total Acres = 2,823.44 acres more or less.

The following parcels are identified for exchange of only the surface estate:

Mount Diablo Meridian, California

T. 13S., R. 9E.,
Sec. 34; SW¼NE¼.
T. 14S., R. 7E.,
Sec. 13; SW¼NE¼, SE¼NW¼.
T. 14S., R. 8E.,
Sec. 18; Lots 1 & 5.
T. 14S., R. 9E.,
Sec. 2; Lots 3 & 4, S½NW¼, S½SW¼;
Sec. 3; Lots 1, 2, 6, 7, 8, 9, 10, & 13;
Sec. 4; Lots 1, 2, 3, 4, 7, 10, & 14;
Sec. 10; Lot 1;
Sec. 11; NW¼NW¼;
Sec. 12; Lots 3, 4, 6, 9, 10, 11, & 16;
Sec. 13; Lots 1, 6, 7, 8, 9 & 10.
T. 14., R. 10E,
Sec. 6; Lots 9 & 18;
Sec. 7; Lots 5, 6, 7, & 8, SE¼NW¼, E½SW¼, W½SE¼;
Sec. 18; Lot 8, NE¼NE¼, E½NW¼.
T. 16S., R. 4E.,
Sec. 7; Lot 1;
Sec. 18; Lots 6, 7, 9 & 10, SE¼SW¼, SW¼SE¼;
Sec. 19; Lots 1, 2, 3, 4, 7, 8, 9 & 16;
Sec. 20; NW¼NW¼, SW¼SW¼.
T. 16S., R. 6E.,
Sec. 21; E½SE¼;
Sec. 22; SW¼;
Sec. 28; E½NW¼, E½SW¼, SW¼SW¼, SE¼;
Sec. 29; NW¼SE¼, SE¼SE¼;
Sec. 32; SE¼NE¼;
Sec. 33; All;
Sec. 34; W½W½
T. 17S., R. 6E.,
Sec. 3; Lot 4.
T. 17S., R. 7E.,
Sec. 34; E½SE¼.
T. 17S., R. 11E.,
Sec. 17; Lots 6, 10, 11, 14 & 15;
Sec. 20; Lots 3, 7 & 10;
Sec. 21; Lots 6, 10, 11, 14 & 15;
Sec. 22; Lots 9, 10, 11, 12, 13, 14 & 15;
Sec. 23; Lots 5, 6 & 8;
Sec. 24; Lots 8, 9, 10, 11 & 12;
Sec. 27; Lots 5, 6, 7, 8, 11 & 12;
Sec. 28; Lots 5, 6, 14 & 15;
Sec. 29; Lots 1 & 8;
Sec. 33; Lots 2 & 3;
Sec. 34; Lot 3.
T. 17S., R. 12E.,
Sec. 19; Lots 1, 4, 5, 6, 7, 8, 9, 10, 11, 12, 15, 19 & 20;
Sec. 20; Lots 11, 12, 13, 14 & 15;
Sec. 29; NW¼.
T. 18S., R. 7E.,
Sec. 4; SE¼NE¼, NE¼SE¼;
Sec. 10; SE¼NW¼.
T. 18S., R. 9E.,
Sec. 33; S½SE¼.
T. 18S., R. 10E.,
Sec. 13; portion of E½E½W½.
T. 19S., R. 6E.,
Sec. 23; NW¼SE¼.

T. 20S., R. 10E.,
Sec. 5; Lot 9.
T. 20S., R. 11E.,
Sec. 25; Lot 1;
Sec. 34; Lot 1, 2 & 6.
T. 21S., R. 13E.,
Sec. 7; Lot 4, SE¼;
Sec. 8; NW¼SW¼;
Sec. 17; SW¼NE¼, W½NW¼, SE¼SE¼;
Sec. 18; E½NE¼, SW¼NE¼;
Sec. 20; E½NE¼;
Sec. 21; W½NW¼, SE¼NW¼, SE¼SE¼;
Sec. 22; SW¼SW¼.
T. 22S., R. 12E.,
Sec. 18; Lot 1.
T. 22S., R. 13E.,
Sec. 1; W½SW¼;
Sec. 11; N½NE¼;
Sec. 12; N½NW¼, SE¼NW¼.
T. 22S., R. 14E.,
Sec. 7; NE¼SW½;
Sec. 8; SW¼NW¼.

Total acres=8,437.65 acres more or less.

In exchange for these lands, the Federal Government will acquire the surface estate of non-Federal lands in Fresno and San Benito Counties from CAL-BLMX, Inc. described as follows:

Mount Diablo Meridian, California

T. 15S., R.12E.,
Sec. 33; NW¼SW¼, SE¼SW¼.
T. 16S., R. 12E.,
Sec. 3; SE¼;
Sec. 4; W½NW¼, NW¼SW¼;
Sec. 8; E½W½;
Sec. 9; NE¼NE¼, SW¼NE¼, N¼SW¼;
Sec. 11; SE¼;
Sec. 12; W½SW¼, SE¼SW¼;
Sec. 13; NW¼NW¼;
Sec. 14; N½N½, S½NW¼, SW¼NE¼, SE¼;
Sec. 15; N½NW¼, W½NE¼;
Sec. 16; All;
Sec. 22; NE¼NW¼, S½N½, N½S½, SW¼SE¼, S½SW¼.
T. 16S., R. 13E.,
Sec. 14; All;
Sec. 16; All;
Sec. 22; N½NW¼, NE¼;
Sec. 24; S½, NE¼, NW¼;
Sec. 26; NE¼, N½NW¼;
Sec. 36; NE¼, E½NW¼, NW¼NW¼, E½SW¼, SE¼.
T. 16S., R. 14E.,
Sec. 30; Lots 1, 2, 3, 4, E½, E½;NW¼, E½SW¼;
Sec. 32; All.
T. 17S., R. 12E.,
Sec. 36; W½NE¼, NE¼NE¼, NW¼, S½S½, NW¼SW¼.
T. 17S., R. 13E.,
Sec. 12; SW¼;
Sec. 16; All;
Sec. 20; SW¼SW¼;
Sec. 23; W½NE½, NE¼NE¼, SW¼, W½SE¼;
Sec. 24; NE¼, NW¼SE¼;
Sec. 25; All;
Sec. 26; S½;
Sec. 27; All;
Sec. 28; All;
Sec. 29; All;
Sec. 30; Lots, 1, 2, 3, 4, E½E½;
Sec. 31; Lot 1. NE¼NE¼;
Sec. 32; All;
Sec. 33; All;
Sec. 34; W½, E½E½;
Sec. 35; All;
Sec. 36; N½, SW¼.
T. 17S., R. 14E.,
Sec. 4; Lots 1, 2, 3, 4, 5, 6, 7, 8, S½;
Sec. 6; Lots 1, 2, 10, 11, E½SE¼;
Sec. 8; E½NW¼, S½;
Sec. 10; S½;
Sec. 14; W½;
Sec. 16; All;
Sec. 18; E½NW¼, NE¼SW¼, NW¼SE¼;
Sec. 20; N½, SW¼, W½SE¼;
Sec. 22; NW¼;
Sec. 26; All;
Sec. 28; N½, N½SE¼, S½SE¼SE¼;
Sec. 29; N½;
Sec. 30; N½;
Sec. 33; NE¼NE¼NE¼;
Sec. 34; N½N½;
Sec. 35; N½N½;
Sec. 36; N½NW¼NE¼, Port. N½NE¼N E¼, N½N½NW¼.
T. 18S., R. 10E.,
Sec. 23; E½NE¼.
T. 18S., R. 13E.,
Sec. 1; Lots 1, 2, 3, 4, S½N½, S½;
Sec. 2; Lots 1, 2, 3, 4, S½N½, S½;
Sec. 3; Lots 1, 2, 3, 4, S½N½, S½;
Sec. 4; Lots 1, 2, 3, 4, S½N½, SW¼;
Sec. 5; Lots 1, 2, 3, 4, S½N½, S½;
Sec. 6; Lots 1, 2, 3, 4, 5, SE¼NE¼;
Sec. 12; N½N½.

Total = 23,507.95 acres more or less.

The federal government will also acquire both the surface and mineral estate of non-Federal lands in San Benito County from CAL-BLMX, Inc. described as follows:

Mount Diablo Meridian, California

T. 18 S., R. 11 E.,
Sec. 16; S½SW¼, NE¼SW¼, SE¼.

Total=280 acres.

SUPPLEMENTARY INFORMATION: The primary purpose of this exchange is (1) to acquire habitat for several threatened or endangered species including the San Joaquin woollythreads (*Lembertia congdonii*), San Benito evening primrose *Camissonia benitensis*), giant kangaroo rat (*Dipodomys ignens*), blunt-nosed leopard lizard (*Gambelia silus*), and San Joaquin kit fox (*Vulpus macrotis mitica*), (2) to enhance regional biodiversity objectives by acquiring disjunct Mojave Desert vegetation, unique stands of turbinella oak and turbinella oak/blue oak hybrids, and a cross-section of Diablo Range ecosystems ranging from Jeffrey/Coulter/Digger pine forests to alkali desert shrub communities, (3) to acquire significant prehistoric archaeological sites, (4) to acquire six miles of riparian habitat, and (5) to enhance public recreation opportunities by acquiring key parcels that improve public access to existing public lands.

Federal lands identified for disposal are generally small isolated parcels without public access and with low public resource values. The exchange is consistent with the Bureau's land use plans for the lands involved. The public interest will be well served by making the exchange.

Lands to be transferred from the United States will be subject to the following reservations, terms, and conditions:

(1) A reservation to the United States for a right-of-way for ditches and canals constructed under the authority of the Act of August 20, 1890 (43 U.S.C. 945).

(2) Authorized pipelines, power lines, roads, highways, telephone lines, minerals leases, and any other authorized land uses will be identified as prior existing rights.

(3) All necessary clearances for archaeology, rare plants and animals shall be completed prior to conveyance of title.

(4) Grazing operations that will have their allotments affected by this exchange are entitled to a 2-year adjustment period. However, a lessee may waive this 2-year notice.

This notice, as provided in 43 CFR 2201.1(b), shall segregate the public lands that are being considered for this exchange. By publication of this notice, those vacant, unappropriated and unreserved public lands described above are segregated from settlement, location and entry under the public lands laws, including the mining laws, but not the mineral leasing laws. The segregative effect shall terminate upon issuance of patent, or upon publication in the **Federal Register** of a termination of the segregation, or two (2) years from the date of this notice, whichever occurs first. This action is necessary while eliminating conflicting encumbrances on the public lands during exchange processing.

Detailed information concerning the exchange, including the environmental assessment, is available at the Hollister Resource Area Office, 20 Hamilton Court, Hollister, CA 95023.

For a period of 45 days from publication of this notice in the Federal Register, interested parties may submit comments to the Area Manager, Hollister Resource Area at the above address. Comments should specify the specific parcel affected by the comment. Any adverse comments will be evaluated by the District Manager, who may vacate or modify this realty action and issue a final determination. In the absence of any action by the District Manager, this action will become the final determination.

FOR FURTHER INFORMATION CONTACT: Steve Addington, Hollister Resource

Area Office, (406) 637–8183 or at the address above.

Robert E. Beehler,

Hollister Area Manager.

[FR Doc. 91–30651 Filed 12–23–91; 8:45 am]

BILLING CODE 4310–41–M

[WY–940–4730–12]

Filing of Plats of Survey: Wyoming

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The plats of survey of the following described lands are scheduled to be officially filed in the Wyoming State Office, Cheyenne, Wyoming, thirty (30) calendar days from the date of this publication.

Sixth Principal Meridian, Wyoming

T. 51 N., R. 96 W., accepted December 11, 1991

T. 51 N., R. 71 W., accepted December 11, 1991

T. 51 N., R. 95 W., accepted December 11, 1991

If protests against a survey, as shown on any of the above plats, are received prior to the official filing, the filing will be stayed pending consideration of the protest(s) and or appeal(s). A plat will not be officially filed until after disposition of protest(s) and or appeal(s).

These plats will be placed in the open files of the Wyoming State Office, Bureau of Land Management, 2515 Warren Ave., Cheyenne, Wyoming, and will be available to the public as a matter of information only. Copies of the plats will be made available upon request and prepayment of the reproduction fee of $2.00 per copy.

A person or party who wishes to protest a survey must file with the State Director, Bureau of Land Management, Cheyenne, Wyoming, a notice of protest prior to thirty (30) calendar days from the date of this publication. If the protest notice did not include a statement of reasons for the protest, the protestant shall file such a statement with the State Director within thirty (30) calendar days after the notice of protest was filed.

The above-listed plats represent dependent resurveys, surveys and subdivisions.

FOR FURTHER INFORMATION CONTACT: Bureau of Land Management, P.O. Box 1828, 2515 Warren Avenue, Cheyenne, Wyoming 82003.

Dated: December 11, 1991.

John P. Lee,

Chief, Branch, of Cadastral Survey.

[FR Doc. 91–30615 Filed 12–23–91; 8:45 am]

BILLING CODE 4310–22–M

Fish and Wildlife Service

Information Collection Submitted to the Office of Management and Budget for Review Under the Paperwork Reduction Act

The proposal for the collection of information listed below has been submitted to the Office of Management and Budget (OMB) for approval under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35). Copies of the proposed information collection requirement and related forms and explanatory material may be obtained by contacting the Service's clearance officer at the phone number listed below. Comments and suggestions on the requirement should be made directly to the Service Clearance Officer and the Office of Management and Budget Paperwork Reduction Project (FWS–002), Washington, DC 20503, telephone 202–395–7340.

Title: Importation Certification for Live Fish and Fish Eggs, 50 CFR 16.13.

OMB Approval Number: N/A.

Abstract: Regulations found in 50 CFR 16.13, implement the Lacey Act, and require that shipments to the United States of live fish and fish eggs, gametes, or uneviscerated dead fish of the family Salmonidae be accompanied by a certificate in English stating that the shipment has been inspected at its origin and is free of certain fish pathogens. These certificates must be singed by an individual previously approved and listed by the Director of the U.S. Fish and Wildlife Service. This certification supports protective regulations to prevent the introduction of certain listed fish pathogens into the United States that may cause disease in wild or cultured fish. The information on the certificate informs U.S. customs and Fish and Wildlife inspectors, located at the ports of entry, of the contents an origins of the shipment, its routing, and its destination. the weight of the shipment, the date the fish lots were inspected for listed pathogens, the location where laboratory diagnostic work was done, and arrival dates.

Service Form Number: No form required.

Frequency: On occasion.

Description of Respondents: Business or other for profit, non-profit institutions, and small businesses or organizations.

Estiamted Completion Time: 20 minutes.

Annual Responses: 180.

Annual Burden Hours: 60.

Service Clearance Officer: James E. Pinkerton, 703–358–1943, Mail Stop—224 Arlington Square, U.S. Fish and Wildlife Service, Washington, DC 20240.

Dated: November 13, 1991.

Noreen K. Clough,

Acting Assistant Director—Fisheries.

[FR Doc. 91–30616 Filed 12–23–91; 8:45 am]

BILLING CODE 4310–55–M

Information Collection Submitted to the Office of Management and Budget for Review Under the Paperwork Reduction Act

The proposal for the collection of information listed below has been submitted to the Office of Management and Budget (OMB) for approval under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35). Copies of the proposed information collection requirement and related forms and explanatory material may be obtained by contacting the Service's clearance officer at the phone number listed below. Comments and suggestions on the requirement should be made directly to the Service Clearance Officer and the Office of Management and Budget, Paperwork Reduction Project (1018–0005), Washington, DC 20503, telephone 202–395–7340.

Titie: Bird Band Recovery Report.

OMB Approval Number: 1018–0005.

Abstract: The use of banding and band recovery information is one of the most important tools used in the preparation of annual United States and Canadian hunting and shooting regulations. Form 3–1807 is used by licensed bird banders and professional wildlife agency personnel on the recovery of Service bands and markers used on marked birds that were shot, found dead, found injured, and foreign retraps. The information collected is also used by Federal, State and private conservation organizations and the Canadian Wildlife Service for the proper management of migratory birds in North America.

Service Form Number: 3–1807.

Frequency: On occasion.

Description of Respondents: Individuals and households, Federal, State, and Provincial personnel.

Estimated Completion Time: 3 minutes.

Annual Responses: 50,000.
Annual Burden Hours: 2,500.
Service Clearance Officer: James E. Pinkerton, 703–358–1943, Mail Stop—224 Arlington Square, U.S. Fish and Wildlife Service, Washington, DC 20240.

Dated: November 21, 1991.

David Olsen,

Assistant Director—Refuges and Wildlife.

[FR Doc. 91–30617 Filed 12–23–91; 8:45 am]

BILLING CODE 4310–55–M

National Park Service

Farmington Wild and Scenic River Study, Massachusetts and Connecticut, Farmington River Study Committee; Meeting

Notice is hereby given in accordance with the Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770, 5 U.S.C. app. 1 s. 10), that a meeting of the Farmington River Study Committee will be held Thursday, February 13, 1992.

The Committee was established pursuant to Public Law 99–590. The purpose of the Committee is to consult with the Secretary of the Interior and to advise the Secretary in conducting the study of the Farmington River segments. The meeting will convene at 7:30 p.m. at the Barkhamsted Elementary School (cafeteria), Barkhamsted, Ct. (The Elementary School is located on route 318 in Pleasant Valley, just west of the intersection with route 181 and the Farmington River.)

Agenda

I. Welcome, introductions—Skip Rogers.
II. Approval of minutes from 11/7/91 meeting.
III. Water Resources Subcommittee—Discussion regarding instream flow study.
IV. River Conservation Planning Subcommittee—Update on local activity (town meetings, zoning regulations, etc.).
V. Update on preparation of Draft Study Report.
VI. Opportunity for public comment.
VII. Other business.
A. Next meeting dates and locations.
B. Reappointments.

Dated: December 16, 1991.

Carol F. Aten,

Acting Regional Director.

[FR Doc. 91–30719 Filed 12–23–91; 8:45 am]

BILLING CODE 4310–70–M

Gettysburg National Military Park Advisory Commission

AGENCY: Gettysburg National Military Park Advisory Commission, National Park Service, Interior.

ACTION: Notice of meeting.

SUMMARY: This notice sets forth the date of the second meeting of the Gettysburg National Military Park Advisory Commission.

DATES: January 30, 1992.

TIME: 1 p.m.–3 p.m.

INCLEMENT WEATHER RESCHEDULE DATE: None.

ADDRESSES: Holiday Inn, 516 Baltimore Street, Gettysburg, Pennsylvania 17325.

FOR FURTHER INFORMATION CONTACT: Jose A. Cisneros, Superintendent, Gettysburg National Military Park, P.O. Box 1080, Gettysburg, Pennsylvania 17325.

SUPPLEMENTARY INFORMATION: The meeting will be open to the public. Any member of the public may file with the Commission a written statement concerning agenda items. The statement should be addressed to the Advisory Commission, Gettysburg National Military Park, P.O. Box 1080, Gettysburg, Pennsylvania 17325. Minutes of the meeting will be available for inspection four weeks after the meeting at the permanent headquarters of the Gettysburg National Military Park located at 95 Taneytown Road, Gettysburg, Pennsylvania 17325.

John Bond,

Acting Regional Director, Mid-Atlantic Region.

[FR Doc. 91–30682 Filed 12–23–91; 8:45 am]

BILLING CODE 4310–70–M

National Register of Historic Places; NHL Boundaries

December 18,1991.

The National Park Service has been working to establish boundaries for all National Historic Landmarks for which no specific boundary was identified at the time of designation and therefore are without a clear delination of the amount of property involved. The results of such designation make it important that we define specific boundaries for each landmark.

In accordance with the National Historic Landmark program regulations part 36 CFR 65, the National Park Service notifies owners, public officials and other interested parties and provides them with an opportunity to make comments on the proposed boundaries.

The 60-day comment period on the attached National Historic Landmark has ended, and the boundaries have been established. Copies of the documentation of the landmark and its boundaries, including maps, may be obtained from Jerry L. Rogers, Associate Director, Cultural Resources, and Keeper of the National Register of Historic Places, National Park Service, P.O. Box 37127, Washington, DC 20013–7127, Attention: Chief of Registration (Phone: 202–343–9536).

Carol D. Shull,

Chief of Registration, National Register of Historic Places, Interagency Resources Division.

Approved boundaries for: Wailua Complex of Heiau, Kauai Island, Hawaii, Designated a Landmark on December 12, 1962.

This property consists of the following five heiaus located on the Wailua River:

Geographical Data

Map A: Quadrangle name: USGS Kapaa, Hawaii 7.5' (1983).
Quadrangle scale: 1:24000.

Hikinaakala Heiau/Hauola Place of Refuge and Petroglyphs

Acreage of nominated property: 2.3 acres.
UTM References: A: Zone 04; Easting 465135; Northing 2438000.

Malae Heiau

Acreage of nominated property: 2 acres.
UTM References; A: Zone 04; Easting 464750; Northing 2438090.

Holoholoku Heiau and Pokhaku Hoohanau

Acreage of nominated property: 1+ acre.
UTM References: A: Zone 04; Easting 464700; Northing 2438680.

Poliahu Heiau

Acreage of nominated property: 1+ acre.
UTM References: A: Zone 04; Easting 463022; Northing 2438380.

Bellstone

Acreage of nominated property: 10 sq. ft.
UTM Reference: A: Zone 04; Easting 463650; Northing 2438660.

[FR Doc. 91–30673 Filed 12–23–91; 8:45 am]

BILLING CODE 4310–70–M

National Register of Historic Places; NHL Boundaries

December 18, 1991.

The National Park Service has been working to establish boundaries for all

National Historic Landmarks for which no specific boundary was identified at the time of designation and therefore are without a clear delineation of the amount of property involved. The results of such designation make it important that we define specific boundaries for each landmark.

In accordance with the National Historic Landmark program regulations 36 CFR part 65, the National Park Service notifies owners, public officials and other interested parties and provides them with an opportunity to make comments on the proposed boundaries.

The 60-day comment period on the attached National Historic Landmarks has ended, and the boundaries have been established. Copies of the documentation of the landmark and its boundaries, including maps, may be obtained from Jerry L. Rogers, Associate Director, Cultural Resources, and Keeper of the National Register of Historic Places, National Park Service, P.O. Box 37127, Washington, DC 20013–7127, Attention: Chief of Registration (Phone: 202–343–9536).

Carol D. Shull,

Chief of Registration, National Register of Historic Places, Interagency Resources Division.

Approved Boundaries for: Long Wharf and Custom House Block National Historic Landmark, Boston, Massachusetts. Designated a Landmark on November 13, 1966.

Beginning at the intersection of the outer line of the southern bulkhead of Long Wharf and a line of convenience parallel to and 40 feet west of the west wall of the brick warehouse known as the Chart House; Thence, northerly along said line of convenience 180 feet to a point; thence; easterly along a second line of convenience drawn at a right angle to the first approximately 170 feet to the northern bulkhead of Long Wharf; thence easterly along the outer line of said northern bulkhead of Long Wharf (approximately 430 feet), southerly along the the outer line of the eastern bulkhead of Long Wharf (approximately 220 feet), and westerly along the outer line of the southern bulkhead of Long Wharf (approximately 580 feet) to the point of beginning.

[FR Doc. 91–30672 Filed 12–23–91; 8:45 am]

BILLING CODE 4310–70–M

National Register of Historic Places; Proposed NHL Boundaries

December 18, 1991.

The National Park Service has been working to establish boundaries for all National Historic Landmarks for which no specific boundary was identified at the time of designation, and therefore, are without a clear delineation of the amount of property involved. The results of such designation make it important that we define specific boundaries for each landmark.

In accordance with the National Historic Landmark program regulations 36 CFR part 65, the National Park Service notifies owners, public officials and other interested parties and provides them with an opportunity to make comments on the proposed boundaries.

Comments on the proposed boundaries will be received for 60 days after the date of this notice. Please address replies to Jerry L. Rogers, Associate Director, Cultural Resources, and Keeper of the National Register of Historic Places, National Park Service, P.O. Box 37127, Washington, DC 20013–7127, Attention: Chief of Registration (202) 343–9536. Copies of the documentation of the landmarks and their proposed boundaries, including maps may be obtained from that same office.

Carol D. Shull,

Chief of Registration, National Register of Historic Places, Interagency Resources Division.

Proposed boundaries for:

Skagway and White Pass District
Skagway-Angoon-Yakutat Division, Alaska
Designated a Landmark on June 13, 1962

Commencing at Bench Mark "Shaft" in T28S, R59E, Copper River Meridian (CRM), the boundary follows a line one-half mile east of the center of the Skagway River in a northerly direction to the confluence of the White Pass Fork. From the confluence the boundary runs one-half mile east of the center of the roadbed of the White Pass and Yukon Railway to Monument 116 on the Alaska-Canada border and then northwest along the border to a point one-half mile west of Monument 117. From this point the boundary follows a line one-half mile west of the center of White Pass Fork in a southerly direction to the confluence of the Skagway River, thence along a line one-half mile west of the center of the Skagway to Bench Mark "Sharp", and from this point southwest to Bench Mark "Shaft." For the purposes of this description, in case more than one river channel exists, the center of eastern most channel represents the 'center of the Skagway River'. In the case of the White Pass Fork, the "center of the fork" is the center of the western channel.

[FR Doc. 91–30686 Filed 12–23–91; 8:45 am]

BILLING CODE 4310–70–M

National Register of Historic Places; Proposed NHL Boundaries

December 18, 1991.

The National Park Service has been working to establish boundaries for all National Historic Landmarks for which no specific boundary was identified at the time of designation, and therefore, are without a clear delineation of the amount of property involved. The results of such designation make it important that we define specific boundaries for each landmark.

In accordance with the National Historic Landmark program regulations 36 CFR Part 65, the National Park Service notifies owners, public officials and other interested parties and provides them with an opportunity to make comments on the proposed boundaries.

Comments on the proposed boundaries will be received for 60 days after the date of this notice. Please address replies to Jerry L. Rogers, Associate Director, Cultural Resources, and Keeper of the National Register of Historic Places, National Park Service, P.O. Box 37127, Washington, DC 20013–7127, attention: Chief of Registration (202) 343–9536. Copies of the documentation of the landmarks and their proposed boundaries, including maps may be obtained from that same office.

Carol D. Shull,

Chief of Registration, National Register of Historic Places, Interagency Resources Division.

Proposed boundaries for:

Lower Klamath National Wildlife Refuge
Siskiyou County, California, and Klamath County, Oregon
Designated a Landmark on January 12, 1965

The Landmark boundary coincides with the legal boundaries of the Lower Klamath Wildlife Refuge.

[FR Doc. 91–30687 Filed 12–23–91; 8:45 am]

BILLING CODE 4310–70–M

National Register of Historic Places; Proposed NHL Boundaries

December 18, 1991.

The National Park Service has been working to establish boundaries for all National Historic Landmarks for which no specific boundary was identified at the time of designation, and therefore, are without a clear delineation of the amount of property involved. The results of such designation make it important

that we decline specific boundaries for each landmark.

In accordance with the National Historic Landmark program regulations 36 CFR part 65, the National Park Service notifies owners, public officials and other interested parties and provides them with an opportunity to make comments on the proposed boundaries.

Comments on the proposed boundaries will be received for 60 days after the date of this notice. Please address replies to Jerry L. Rogers, Associates Director, Cultural Resources, and Keeper of the National Register of Historic Places, National Park Service, P.O. Box 37127, Washington, DC 20013–7127, Attention: Chief of Registration (202) 343–9536. Copies of the documentation of the landmarks and their proposed boundaries, including maps may be obtained from that same office.

Carol D. Shull,

Chief of Registration, National Register of Historic Places, Interagency Resources Division.

Proposed boundaries for:

Chilkoot Trail and Dyea Taiya River Valley, Alaska Designated a Landmark on June 16, 1978

Beginning at Bench Mark "Lame" in T28S R59E, Copper River Meridian (CRM), thence in a northerly direction along a line one-half mile east of the center of the Taiya River to a point on the U.S. Canadian Border one-half mile southeast of Monument 120 in T25S, R60E, CRM, thence northwest along the U.S.-Canadian border for a distance of one mile, thence in a southerly direction along a line one-half mile west of the center of the Taiya River to a point due west of Bench Mark "Lame," thence due east to Bench Mark "Lame." Where the Taiya River has more than one channel running side-by-side, the "center" of the river is the center of the easternmost channel for purposes of the eastern boundary line of this description and the "center" of the river is the center of the westernmost channel for purposes of the western boundary line of this description.

[FR Doc. 91–30688 Filed 12–23–91; 8:45 am]

BILLING CODE 4310–70–M

National Register of Historic Places; Notification of Pending Nominations

Nominations for the following properties being considered for listing in the National Register were received by the National Park Service before December 14, 1991. Pursuant to § 60.13 of 36 CFR part 60 written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded to the National Register, National Park Service, P.O. Box 37127, Washington, DC 20013–7127. Written comments should be submitted by January 8, 1992.

Carol D. Shull,

Chief of Registration, National Register.

ALASKA

Wrangell-Peterburg Borough-Census Area

CHUGACH (Ranger Boat), Federal Government Dock, Wrangell Narrows, Petersburg, 91001937

ARIZONA

Coconino County

Cooper Ridge Lookout Tree (National Forest Fire Lookouts in the Southwestern Region TR), N of jct. of Alt. US 89 and AZ 67, Kaibab NF, Fredonia vicinity, 91001962

Corral Lake Lookout Tree (National Forest Fire Lookouts in the Southwestern Region TR), Roughly 30 mi. SE of Fredonia, Kaibag NF, Fredonia vicinity, 91001954

Fracas Lookout Tree (National Forest Fire Lookouts in the Southwestern Region TR), Roughly 30 mi. SE of Fredonia, Kaibab NF, Fredonia vicinity, 91001955

Grandview Lookout Tree (National Forest Fire Lookouts in the Southwestern Region TR), S of Grandview Pt., Grand Canyon NP, in Kaibab NF, Grand Canyon vicinity, 91001945

Hull Tank Lookout Tree (National Forest Fire Lookouts in the Southwestern Region TR), Se of Grandview Pt., Grand Canyon NP, in Kaibab NF, Grand Canyon vicinity, 91001947

Little Mountain Lookout Tree (National Forest Fire Lookouts in the Southwestern Region TR), Roughly 30 mi. SE of Fredonia, Kaibab NF, Fredonia vicinity, 91001950

Summit Mountain Lookout Tree (National Forest Fire Lookouts in the Southwestern Region TR), Off Perkinsville Rd. SE of Williams, Kaibab NF, Williams vicinity, 91001948

Tater Point Lookout Tree (National Forest Fire Lookouts in the Southwestern Region TR), Forest Rd. 240 E of AZ 67, S of Alt. US 89, Kaibab NF, Fredonia vicinity, 91001946

Telephone Hill Lookout Tree (National Forest Fire Lookouts in the Southwestern Region TR), Off AZ 67 S of jct. with Alt. US 89, Kaibab NF, Fredonia vicinity, 91001952

Tipover Lookout Tree (National Forest Fire Lookouts in the Southwestern Region TR), NW of N. Rim Entrance Station, Grand Canyon NP, in Kaibab NF, Fredonia vicinity, 91001953

Tusayan Lookout Tree (National Forest Fire Lookouts in the Southwestern Region TR), W of US 180, SW of Tusayan, Kaibab NF, Tusayan vicinity, 91001951

CALIFORNIA

Sacramento County

Sacramento Air Depot Historic District, McClellan Air Force Base, North Highlands vicinity, 91001969

DISTRICT OF COLUMBIA

District of Columbia State Equivalent

Franciscan Monastery and Memorial Church of the Holy Land, 1400 Quincy St., NE., Washington, 91001943

Watterston House, 224 2nd St., SE., Washington, 91001942

FLORIDA

Orange County

Twin Mounds Archaeological Districts, Address Restricted, Sorrento vicinity, 91001957

KANSAS

Douglas County

Vermilia-Boener House, NW of jct. of US 24, US 59 and US 40, Lawrence vicinity, 91001961

MASSACHUSETTS

Middlesex County

Shirley Village Historic District, Roughly bounded by Center, Harvard, Leominster and Shaker Rds., Shirley, 91001958

MINNESOTA

Hennepin County

Ogden Apartment Hotel, 66—68 S. 12th St., Minneapolis, 91001956

MISSOURI

Atchison County

St. Oswald's Protestant Episcopal Church, MO EE S of jct. with MO 46, Skidmore vicinity, 91001959

MONTANA

Big Horn County

Camp Four, 11 mi. NE of Fort Smith on Fort Smith—Hardin Co. Rd., Fort Smith vicinity, 91001940

Broadwater County

State Bank of Townsend, 400 Broadway, Townsend, 91001941

Gallatin County

Green, Jesse R., Homestead, 6 mi. NE of Trident, Trident vicinity, 91001939

Judith Basin County

Meadowbrook Stock Farm, US 87, Hobson vicinity, 91001938

NEW YORK

Broome County

Highland Park Carousel (Broome County Carousels MPS), Highland Park, Cooper Rd., Endwell vicinity, 91001963

Johnson, C. Fred, Park Carousel (Broome County Carousels MPS), C. Fred Johnson Park, Johnson City, 91001968

Johnson, George F., Recreation Park Carousel (Broome County Carousels MPS), George F. Johnson Recreation Park, Binghamton, 91001967

Johnson, George W., Park Carousel (Broome County Carousels MPS), George W Johnson Park, Endicott, 91001964

Ross Park Carousel (Broome County Carousels MPS), Ross Park, Binghamton, 91001966
West Endicott Park Carousel (Broome County Carousels MPS), West Endicott Park, Endicott vicinity, 91001965

NORTH CAROLINA

Forsyth County

Washington Park Historic District, Roughly bounded by Leonard St., Acadia Ave., Sunnyside Ave., Broad St., Bond St. and Washington Park, Winston-Salem, 91001960

[FR Doc. 91-30611 Filed 12-23-91; 8:45 am]
BILLING CODE 4310-70-M

INTERSTATE COMMERCE COMMISSION

[Ex Parte No. MC-5 (Sub-No. 2) Ex Parte No. 159 (Sub-No. 1)]

Motor Carrier and Freight Forwarder Insurance Procedures and Minimum Amounts of Liability

AGENCY: Interstate Commerce Commission.

ACTION: Notice.

SUMMARY: The Commission reminds the public that its rules prohibit companies that fail to pay delinquent insurance filing processing fees from making additional security filings with the Commission pending collection of delinquent accounts.

EFFECTIVE DATE: January 5, 1992.

FOR FURTHER INFORMATION CONTACT: E.C. Fernandez, (202) 927-5638, or Jean Jackson, (202) 927-6327 [TDD for hearing impaired: (202) 927-5721].

SUPPLEMENTARY INFORMATION: Commission records indicate that numerous companies filing certificates of insurance under credit accounts with the Commission have delinquent accounts. In an effort to collect these delinquent fees the Commission, on December 4, 1991, sent letters to delinquent account holders demanding payment, proof of payment, or proof of any affirmative defense to payment by January 5, 1992. The letter enclosed supporting documentation. The letter also indicated that failure to comply would result in freezing of the account, rejection of future certificate filings, and Commission pursuit of all available remedies. See Insurance Procedures and Minimum Amounts of Liability, 133 M.C.C. 273 (1983). The Commission anticipates prompt compliance to minimize costly and burdensome pursuant of alternatives by the Commission and disruption to the insurance companies and their customers.

Decided: December 18, 1991.

By the Commission, Sidney L. Strickland, Jr., Secretary.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 91-30645 Filed 12-23-91; 8:45 am]
BILLING CODE 7035-01-M

JUDICIAL CONFERENCE OF THE UNITED STATES

Proposed Amended Rules for the Processing of Certificates That a Judicial Officer Might Have Engaged in Impeachable Conduct

AGENCY: Judicial Conference of the United States.

ACTION: Request for comments.

SUMMARY: The Judicial Conference Committee to Review Circuit Council Conduct and Disability Orders proposes an amendment to its rules for the Processing of Certificates that a Judicial Officer Might Have Engaged in Impeachable Conduct, adopted in September, 1987. The recommended change implements the recent amendment to the Judicial Conduct and Disability Act, 28 U.S.C. 372(c)(8)(B), vesting the Conference with authority to originate its own determination to the House of Representatives, without the necessity of referral or certification by a circuit judicial council under section 372(c)(7), that consideration of impeachment may be warranted, where a judge has been convicted of a felony and has exhausted or waived all means of direct review thereof.

DATES: Written comments on these rules should be received on or before January 31, 1992.

ADDRESS: Comments should be mailed to the Office of the General Counsel, Administrative Office of the United States Courts, Washington, DC 20544.

FOR FURTHER INFORMATION CONTACT: William R. Burchill, Jr., General Counsel, Administrative Office of the United States Courts, Washington, DC 20544, telephone: FTS/202 633-6127.

Rules for the Processing of Certificates From Judicial Councils That a Judicial Officer Might Have Engaged in Impeachable Conduct

The conference approved the following amended Rules for the Processing of Certificates from Judicial Councils that a Judicial Officer Has Engaged in Conduct that Might Constitute Grounds for Impeachment:

1. When a certificate from a judicial council that a judicial officer has engaged in conduct that might constitute grounds for impeachment is premised entirely upon a judgment of conviction in a criminal case, or when the Judicial Conference is otherwise informed that a judge or judicial officer has been convicted of a felony, and the judgment has become final by the exhaustion or termination of all rights of direct judicial review, the Judicial Conference, in its discretion, may accept the final judgment as conclusive and, without notice to the accused judicial officer, may make its own determination by a majority vote as to whether or not it will forward a final certificate to the House of Representatives of the United States Congress.

2. Except when the Judicial Conference of the United States determines that the full Conference should act upon the matter pursuant to Rule 1, all such certification matters shall be referred to in the first instance, by the Conference or its Executive Committee, to an *ad hoc* committee of Conference members or to the Committee to Review Circuit Council Conduct and Disability Orders for processing and the preparation of a report with recommendations back to the Conference.

3. When a certification proceeding is referred to a committee for a report and recommendation as provided in Rule 2, the relevant committee shall (1) provide the accused judicial officer with a copy of the certificate and a copy of all papers filed with the Judicial Conference in support of the certificate unless a copy of all such documents has previously been furnished to the accused judicial officer, or (2) in its discretion, make all such papers available for inspection by the judicial officer and his or her counsel in the Administrative Office in Washington, DC, or some other convenient, designated place.

4. The accused judicial officer shall have sixty days within which to file a written response to the certificate. The sixty-day period will begin to run when (1) a copy of all relevant papers is furnished or made available for inspection, or (2) when he or she is given written notice of the right to file such a written response, whichever later occurs. For good cause, the committee may extend the time within which a written response may be filed.

5. The Committee may receive written argument from a complainant if the

committee determines that it may be assisted by such receipt.

6. Oral argument ordinarily will not be allowed, but may be allowed if the committee determines that it would be assisted by it.

7. In the preparation and filing of the written response and in oral argument, if allowed, the judicial officer is entitled to representation by counsel of choice at his or her expense.

8. (a) If the Judicial Conference or its committee determines that additional investigation is necessary or appropriate, notice that such investigation will be conducted will be given in advance to the accused judicial officer. The notice will be given at least ten days in advance of the commencement of the investigation, unless an emergency situation requires an earlier commencement of investigatory measures.

(b) During the course of any such investigation, the accused judicial officer will be afforded those opportunities as provided in 28 U.S.C. 372(c)(11)(B), and the complainant will be afforded those opportunities as provided in 28 U.S.C. 372(c)(11)(C).

(c) At the conclusion of any such investigation, the investigation panel will file a written report, a copy of which will be furnished the accused judicial officer or made available for his or her inspection and, if the committee decides that it is appropriate, to the complainant. The report of the investigation will be made a part of the record, and the time within which the accused judicial officer may file a written response will not begin to run before a copy of the report is furnished to or made available for inspection by the judicial officer.

9. The committee will file with the Conference a report, including a recommendation or recommendations. The report will be received by the Conference as the reports of other of its committees. The Conference may adopt the report, including its recommendations, in its entirety, or adopt it in part and reject it in part.

10. Since the committee's report is an internal document and an accused judicial officer will already have been given an opportunity to file a full written response to the certificate, a copy of the committee's report need not be furnished to him.

L. Ralph Mecham,

Director.

[FR Doc. 91-30609 Filed 12-23-91; 8:45 am]

BILLING CODE 2210-01-M

DEPARTMENT OF JUSTICE

Lodging of Consent Decree Pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act

In accordance with Departmental policy, 28 CFR 50.7, notice is hereby given that on December 12, 1991, a proposed Consent Decree in *United States* v. *Atochem North America, Inc.*, Civil No. 05533(T), was lodged with the United States District Court for the District of New Jersey. The complaint in this action was filed pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA"), 42 U.S.C. 9601 *et seq.*, to recover costs incurred by the Environmental Protection Agency ("EPA") in taking response actions at the Myers Property Superfund Site ("Site") located in Franklin Township, Hunterdon County, New Jersey.

The proposed Consent Decree embodies an agreement by the potentially responsible party at the Site to pay the United States $2,700,000.00 for past response costs incurred by EPA in connection with the Site. It also requires the potential responsible party to perform the remedial work selected by EPA for Operable Unit I, i.e.: (1) Evacuation and treatment of the contaminated soils, followed by backfilling of the treated soil; (2) decontamination of building surfaces; and (3) interim extraction of contaminated groundwater from the zone of highest contaminant concentration, on-site treatment of the extracted groundwater, and reinjection of the treated water. The proposed Consent Decree also provides for the potentially responsible party to pay for all but the first $800,000 of EPA's costs in overseeing this work, and requires that the potentially responsible party conduct a Focused Groundwater Feasibility Study to evaluate additional, "final" remedial alternatives, if any, for the bedrock water-bearing zone.

The Department of Justice will receive comments relating to the proposed Consent Decree for a period of thirty (30) days from the date of this publication. Comments should be addressed to the Assistant Attorney General of the Environment and Natural Resources Division, Department of Justice, Washington, DC 20530, and should refer to *United States* v. *Atochem North America, Inc.*, DOJ No. 90-11-2-662.

The proposed Consent Decree may be examined at the Region II Office of the Environmental Protection Agency, 26 Federal Plaza, New York, New York 10278, and at the Environmental Enforcement Section Document Center, 601 Pennsylvania Avenue Building, NW., Washington, DC 20004 (202-347-7829).

A copy of the proposed Consent Decree may be obtained in person or by mail from the Environmental Enforcement Section Document Center, 601 Pennsylvania Avenue Building, NW., Box 1097, Washington, DC 20004. In requesting a copy, please refer to the referenced case and enclose a check in the amount of $13.25 (25 cents per page reproduction cost) for the Consent Decree.

John C. Cruden,

Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 91-30607 Filed 12-23-91; 8:45 am]

BILLING CODE 4410-01-M

Lodging of Consent Decree Pursuant to Cercla

In accordance with Department Policy, 28 CFR 50.7, and pursuant to section 122(i) of CERCLA, 42 U.S.C. 9622(i), notice is hereby given that a proposed consent decree in *United States* v. *City of North Miami, Florida*, Civil Action No. 91-2834 was lodged with the United States District of Florida on December 12, 1991. This agreement resolves a judicial enforcement action brought by the United States against the defendant pursuant to sections 106 and 107 of CERCLA, 42 U.S.C. 9606, 9607.

The proposed decree provides that the City of North Miami will design, construct, and operate a remedial action to intercept ammonia leachate that is migrating from the Munisport Landfill into a mangrove preserve. The United States alleges that this ammonia leachate is toxic to certain organisms that inhabit the mangrove preserve, and that the leachate presents or may present an imminent and substantial endangerment to the environment. The City denies that such endangerment exists, but has agreed to perform the remedial measures selected by EPA in order to resolve this lawsuit. The proposed decree also requires that the City of North Miami reimburse the Hazardous Substances Superfund in the amount of $140,000 a partial reimbursement of funds expended by EPA at the site, and that the City pay EPA's oversight costs (up to stated amounts).

The Department of Justice will receive for a period of (30) days from the date of this publication, comments relating to the proposed consent decree. Comments should be addressed to the Assistant Attorney General of the Environment

and Natural Resources Division, Department of Justice, Washington, DC 20530, and should refer to *United States v. City of North Miami, Florida*, D.O.J. Ref. 90–11–3–624.

This Consent Decree may be examined at the offices of the United States Attorney, Southern District of Florida, 155 South Miami Avenue, Miami, Florida 33130, at the Office Regional Counsel, EPA, 345 Courtland Street, NE., Atlanta, Georgia 30365, and at the Offices of the Environmental Enforcement Section, Environment and Natural Resources Division of the Department of Justice, room 1535, Ninth Street and Pennsylvania Avenue, NW., Washington, DC 20530. The proposed consent decree may also be examined at the Environmental Enforcement Section Document Center, 601 Pennsylvania Avenue, Box 1097, NW., Washington, DC 20004, (202) 347–7829. A copy of the proposed consent decree may be obtained in person or by mail from the Document Center. In requesting a copy, please enclose a check in the amount of $12.75 (25 cents per page reproduction costs) payable to Consent Decree Library.

John C. Cruden,

Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 91–30606 Filed 12–23–91; 8:45 am]

BILLING CODE 4410–01–M

DEPARTMENT OF LABOR

Office of the Secretary

Agency Recordkeeping/Reporting Requirements Under Review by the Office of Management and Budget (OMB)

Background

The Department of Labor, in carrying out its responsibilities under the Paperwork Reduction Act (44 U.S.C. chapter 35), considers comments on the reporting/recordkeeping requirements that will affect the public.

List of Recordkeeping/Reporting Requirements Under Review

As necessary, the Department of Labor will publish a list of the Agency recordkeeping/reporting requirements under review by the Office of Management and Budget (OMB) since the last list was published. The list will have all entries grouped into new collections, revisions, extensions, or reinstatements. The Departmental Clearance Officer will, upon request, be able to advise members of the public of the nature of the particular submission they are interested in.

Each entry may contain the following information:

The Agency of the Department issuing this recordkeeping/reporting requirement.
The title of the recordkeeping/reporting requirement.
The OMB and/or Agency identification numbers, if applicable.
How often the recordkeeping/reporting requirement is needed.
Whether small businesses or organizations are affected.
An estimate of the total number of hours needed to comply with the recordkeeping/reporting requirements and the average hours per respondent.
The number of forms in the request for approval, if applicable.
An abstract describing the need for the uses of the information collection.

Comments and Questions

Copies of the recordkeeping/reporting requirements may be obtained by calling the Departmental Clearance Officer, Kenneth A. Mills (202–523–5095). Comments and questions about the items on this list should be directed to Mr. Mills, Office of Information Resources Management Policy, U.S. Department of Labor, 200 Constitution Avenue, NW., room N–1301, Washington, DC 20210. Comments should also be sent to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for (BLS/DM/ESA/ETA/OLMS/MSHA/OSHA/PWBA/VETS), Office of Management and Budget, room 3001, Washington, DC 20503 (202–395–6880).

Any member of the public who wants to comment on recordkeeping/reporting requirements which have been submitted to OMB should advise Mr. Mills of this intent at the earliest possible date.

Revision

Employment and Training Administration

Characteristics of the Insured Unemployed.
1205–0009.
ETA 227.
Quarterly.
State or local governments.
53 respondents; 212 total hours; 20 minutes per form.
1 form.

This report is the only source of current, consistent, demographic information on the UI claimant population. The age, sex, race/ethnic, industry, and occupation variables identify important claimant cohorts for legislative, economic and social planning purposes and evaluation of the UI program on the Federal and State levels.

Extension

Employment Standards Administration

Request from Claimant for Information on Earnings, Dual Benefits, Dependents, and Third Party Settlement.
1215–0151.
CA–1032.
Annually.
Individual or households.
50,000 respondents; 16,667 total hours; ⅓ hour per response. 1 form.

The CA–1032 is used to obtain information from claimants receiving compensation on the Division of Federal Employees' Compensation periodic disability roll. This information is necessary to ensure that the compensation being paid is correct.

Signed at Washington D.C. this 17th day of December, 1991.

Kenneth A. Mills,

Departmental Clearance Officer.

[FR Doc. 91–30638 Filed 12–23–91; 8:45 am]

BILLING CODE 4510–30–M

Labor Advisory Committee for Trade Negotiations and Trade Policy; Meeting

Pursuant to the provisions of the Federal Advisory Committee Act (Pub. L. 92–463 as amended), notice is hereby given of a meeting of the Labor Advisory Committee for Trade Negotiations and Trade Policy.

Date, time and place: January 8, 1992, 10 am—12 noon, rm. S–4215 A&B, Department of Labor Building, 200 Constitution Ave., NW., Washington, DC 20210.

Purpose: To discuss trade negotiations and trade policy of the United States.

This meeting will be closed under the authority of section 10(d) of the Federal Advisory Committee Act and 5 U.S.C. 552(c)(1). The Committee will hear and discuss sensitive and confidential matters concerning U.S. trade negotiations and trade policy.

FOR FURTHER INFORMATION CONTACT: Fernand Lavallee, Director, Trade Advisory Group, Phone: (202) 523–2752.

Signed at Washington, DC this 13th day of December, 1991.

Shellyn G. McCaffrey,

Deputy Under Secretary, International Affairs.

[FR Doc. 91–30641 Filed 12–23–91; 8:45 am]

BILLING CODE 4510–28–M

Employment and Training Administration

[TA-W-26,112]

Outokumpu American Brass, Kenosha, WI; Negative Determination Regarding Application for Reconsideration

By an application dated November 21, 1991, one of the workers requested administrative reconsideration of the subject petition for trade adjustment assistance. The denial notice was signed on September 25, 1991 and published in the **Federal Register** on October 22, 1991 (56 FR 54588).

Pursuant to 29 CFR 90.18(c) reconsideration may be granted under the following circumstances:

(1) If it appears on the basis of facts not previously considered that the determination complained of was erroneous;

(2) If it appears that the determination complained of was based on a mistake in the determination of facts not previously considered; or

(3) If in the opinion of the Certifying Officer, a misinterpretation of facts or of the law justified reconsideration of the decision.

Investigation findings show that the workers produce copper mill products.

The worker claims that the Department used only 1990 import data for determining whether the increased import criterion of the Group Eligibility Requirement was met. The worker also claims that Outokumpu is petitioning the Department of Commerce on anti-dumping suit.

The Department's denial was based on the fact that the increased import criterion as well as the "contributed importantly" test of the Group Eligibility Requirements of the Trade Act were not met. Investigation findings show that U.S. imports of copper mill products decreased in the first half of 1991 compared to the same period in 1990 as well as in 1990 compared to 1989.

The "contributed importantly" test is generally demonstrated through a survey of the workers' firm's customers. The Department's survey of major declining customers shows that the customers who imported copper mill products accounted for an insignificant portion of the subject firm's sales decline during the period under investigation.

Although the Department of Commerce found in 1986 that Canadian and Korean companies were guilty of dumping brass plates and thereby injuring the domestic industry, this, in itself, would not provide a basis for a worker group certification at a particular plant. Further, the Kenosha plant does not produce brass plates.

Company officials at Outokumpu stated that sales and production declines and worker separations at Kenosha are the result of the slow economy especially for automobiles and the need to be more efficient in order to compete against all companies, especially domestic companies.

Conclusion

After review of the application and investigative findings, I conclude that there has been no error or misinterpretation of the law or of the facts which would justify reconsideration of the Department of Labor's prior decision. Accordingly, the application is denied.

Signed at Washington, DC, this 13th day of December 1991.

Robert O. Deslongchamps,

Director, Office of Legislation & Actuarial Services, Unemployment Insurance Service.

[FR Doc. 91-30639 Filed 12-23-91; 8:45 am]

BILLING CODE 4510-30-M

[TA-W-25,608]

Rockwell International Corporation T/A Division New Castle, PA; Revised Determination on Reopening

On June 21, 1991, the Department issued a Negative Determination Regarding Eligibility to Apply for Worker Adjustment Assistance to workers of Rockwell International Corporation, T/A Division in New Castle, Pennsylvania. The notice was published in the **Federal Register** on June 28, 1991 (56 FR 29717).

The workers were also denied on reconsideration. The notice of negative determination on reconsideration was issued on October 21, 1991.

The Department, at the request of Local 4194 of the United Steelworkers, reopened the investigation for workers of Rockwell International Corporation in New Castle, Pennsylvania.

New findings show that workers producing front axle components in Departments #22, #24, #31, #32, #34, #40 and #42 at the Rockwell International Corporation in New Castle, Pennsylvania were separated from employment as a result of corporate outsourcing of components to foreign companies in Europe, Canada and Mexico. Investigation findings show that Rockwell had increased company imports of axle components in the first quarter of 1991.

Other findings on reopening show substantial declines in production and employment from September 1990 to September 1991 in the above mentioned Departments at New Castle.

Other findings show that workers in Departments #33, Knuckle Machining (high volume); #35, Knuckle Machining (low volume) and #51, Front Axle Assembly were not significantly impacted by imports. The findings show that all knuckle machining at New Castle is scheduled to be transferred to other domestic plants. Further, the loss of the P-Van and GMT 455 axles to a domestic firm who foreign sources the axles did not account for a significant portion of assembly production in Department 51, Front Axle Assembly.

Conclusion

After careful consideration of the new facts obtained on reopening it is concluded that increased imports of articles like or directly competitive with front axle components produced by Rockwell International Corporation in New Castle, Pennsylvania contributed importantly to the total or partial separation of workers at Rockwell International. In accordance with the provisions of the Trade Act of 1974, I make the following revised determination:

All workers in Departments #22, #24, #31, #32, #34, #40, and #42 at the Rockwell International Corporation in New Castle, Pennsylvania who became totally or partially separated from employment on or after September 1, 1990 are eligible to apply for adjustment assistance under section 223 of the Trade Act of 1974.

Signed at Washington, DC this 13th day of December 1991.

Robert O. Deslongchamps,

Director, Office of Legislation & Actuarial Services Unemployment Insurance Service.

[FR Doc. 91-30640 Filed 12-23-91; 8:45 am]

BILLING CODE 4510-30-M

Occupational Safety and Health Administration

Shipyard Employment Standards Advisory Committee Meeting

AGENCY: Occupational Safety and Health Administration (OSHA).

ACTION: Notice of meeting.

SUMMARY: Notice is hereby given that the Shipyard Employment Standards Advisory Committee, established under the provisions of the Federal Advisory Committee Act (FACA), as amended (5 U.S.C., App. I) and section 7(b) of the Occupational Safety and Health Act, (29 U.S.C. 656(b)), will convene on Februery 4, 1992, at 8:30 a.m., at the Holiday Inn at the Embarcadero, 1355 North Harbor Drive, San Diego, California 92101. The

meeting will adjourn on February 5, 1992, at approximately 4 p.m. The public is encouraged to attend.

The agenda is as follows:

I. Call to Order.
II. Review the transcripts of November 20 & 21, 1991, meeting.
III. Discussion of the following standards:
(a) AD-HOC Committee Report on 29 CFR part 1915, Subpart G, Materials Handling and Storage (Final Review)
(b) AD-HOC Committee Report on 29 CFR part 1915, Subpart P, Fire Protection
(c) AD-HOC Committee Report on 29 CFR part 1915, Subpart Q, Hazardous Materials
(d) Subpart L. Electrical
1). 1926 subpart K (Temporary wiring)
2). 1910 subpart S (Electrical)
(e) 29 CFR part 1915, subpart F, General Working Conditions
IV. New Business. Discussion of the following standards, as time permits.
(a) Proposed 29 CFR part 1915, subpart Z, Lead.

Time permitting, the Committee will consider oral presentations relating to agenda items. Persons wishing to address the Committee should submit a written request to Mr. Thomas Hall (address below) by the close of business, January 24, 1992. The request must include the name and address of the person wishing to appear, the capacity in which the appearance will be made, a short summary of the intended presentation, and an estimate of the amount of time needed.

FOR FURTHER INFORMATION CONTACT: Mr. Thomas Hall, U.S. Department of Labor, Occupational Safety and Health Administration, Office of Information and Consumer Affairs, room N-3647, 200 Constitution Avenue NW., Washington, DC 20210, (202) 523-8617.

Signed at Washington, DC, this 18th day of December 1991.

Gerard F. Scannell,

Assistant Secretary of Labor.

[FR Doc. 91-30675 Filed 12-23-91; 8:45 am]

BILLING CODE 4510-26-M

DEPARTMENT OF LABOR

Pension and Welfare Benefits Administration

[Exemption Application No. D-8775, et al.]

Prohibited Transaction Exemption 91-72; Grant of Individual Exemptions; Anthony J. Bernardo, Jr. D.D.S., P.A. Profit Sharing Plan, et al.

AGENCY: Pension and Welfare Benefits Administration, Labor.

ACTION: Grant of individual exemptions.

SUMMARY: This document contains exemptions issued by the Department of Labor (the Department) from certain of the prohibited transaction restrictions of the Employee Retirement Income Security Act of 1974 (the Act) and/or the Internal Revenue Code of 1986 (the Code).

Notices were published in the **Federal Register** of the pendency before the Department of proposes to grant such exemptions. The notices set forth a summary of facts and representations contained in each application for exemption and referred interested persons to the respective applications for a complete statement of the facts and representations. The applications have been available for public inspection at the Department in Washington, DC. The notices also invited interested persons to submit comments on the requested exemptions to the Department. In addition the notices stated that any interested person might submit a written request that a public hearing be held (where appropriate). The applicants have represented that they have complied with the requirements of the notification to interested persons. No public comments and no requests for a hearing, unless otherwise stated, were received by the Department.

The notices of proposed exemption were issued and the exemptions are being granted solely by the Department because, effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978) transferred the authority of the Secretary of the Treasury to issue exemptions of the type proposed to the Secretary of Labor.

Statutory Findings

In accordance with section 408(a) of the Act and/or section 4975(c)(2) of the Code and the procedures set forth in 29 CFR part 2570, subpart B (55 FR 32836, 32847, authority 10, 1990) and based upon the entire record, the Department makes the following findings:

(a) The exemptions are administratively feasible;
(b) They are in the interests of the plans and their participants and beneficiaries; and
(c) They are protective of the rights of the participants and beneficiaries of the plans.

Anthony J. Bernardo, Jr., D.D.S., P.A., Profit Sharing Plan (the Plan), Located in Wilmington, Delaware

(Prohibited Transaction Exemption 91-72; Exemption Application No. D-8775).

Exemption

The restrictions of sections 406(a) and 406(b) (1) and (2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code, shall not apply to the sale for cash of a parcel of real property (the Property) from the Plan to Anthony J. Bernardo, Jr. and Mary Ann Bernardo, parties in interest with respect to the Plan, provided the Plan receives no less than the greater of $105,000 or the fair market value of the Property at the time of sale.

For a more complete statement of the facts and representations supporting the Department's decision to grant this exemption, refer to the notice of proposed exemption published on October 23, 1991, at 56 FR 54900.

FOR FURTHER INFORMATION CONTACT: Paul Kelty of the Department, telephone (202) 523-8883. (This is not a toll-free number.)

General Motors Hourly-Rate Employees Pension Plan; and the General Motors Retirement Program for Salaried Employees (together, the Plans), Located in New York, New York

(Prohibited Transaction Exemption 91-73; Exemption Application Nos. D-8577 and D-8578)

Exemption

The restrictions of section 406(a) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (D) of the Code, shall not apply to the purchase on December 19, 1990 by the Plans of a commercial mortgage note (the Note), which is secured by a first deed of trust against certain improved real property, from The Prudential Insurance Company of America, a party in interest with respect to the Plans, for $200,786,511, provided that such amount was not greater than the fair market value of the Note on the date of purchase.

EFFECTIVE DATE: The effective date of this exemption is December 19, 1990.

NOTICE TO INTERESTED PERSONS: The applicant represents that it was unable to notify interested persons within the time period specified in the **Federal Register** notice published on October 2, 1991. The applicant states that all interested persons were notified, in the manner agreed upon between the applicant and the Department, by November 8, 1991. Interested persons were advised that they had until December 9, 1991 to comment on the proposed exemption.

WRITTEN COMMENTS: The Department received four written comments from interested persons. However, the

commenters did not address any specific issues relating to the transaction for which the applicant requests an exemption. Therefore, after consideration of the entire record, the Department has determined to grant the exemption.

For a more complete statement of the facts and representations supporting the Department's decision to grant this exemption refer to the notice of proposed exemption published on October 2, 1991 at 56 FR 49912.

FOR FURTHER INFORMATION CONTACT: Mr. E.F. Williams of the Department at (202) 523–8883. (This is not a toll free number.)

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption under section 408(a) of the Act and/or § 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest or disqualified person from certain other provisions to which the exemption does not apply and the general fiduciary responsibility provisions of section 404 of the Act, which among other things require a fiduciary to discharge his duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(B) of the Act; nor does it affect the requirement of section 401(a) of the Code that the plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries;

(2) These exemptions are supplemental to and not in derogation of, any other provisions of the Act and/or the Code including statutory or administrative exemptions and transactional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of whether the transaction is in fact a prohibited transaction; and

(3) The availability of these exemptions is subject to the express condition that the material facts and representations contained in each application accurately describes all material terms of the transaction which is the subject of the exemption.

Signed at Washington, D.C., this 19th day of December 1991.

Ivan Strasfeld,

Director of Exemption Determinations, Pension and Welfare Benefits Administration, Department of Labor.

[FR Doc. 91–30674 Filed 12–23–91; 8:45 am]

BILLING CODE 4510–29–M

DEPARTMENT OF LABOR

Pension and Welfare Benefits Administration

[Application No. D–8769, et al.]

Proposed Exemptions; Otologic Medical Services, P.C. Profit Sharing Plan, et al.

AGENCY: Pension and Welfare Benefits Administration, Labor.

ACTION: Notice of proposed exemptions.

SUMMARY: This document contains notices of pendency before the Department of Labor (the Department) of proposed exemptions from certain of the prohibited transaction restriction of the Employee Retirement Income Security Act of 1974 (the Act) and/or the Internal Revenue Code of 1986 (the Code).

Written Comments and Hearing Requests

All interested persons are invited to submit written comments or request for a hearing on the pending exemptions, unless otherwise stated in the Notice of Proposed Exemption, within 45 days from the date of publication of this **Federal Register** Notice. Comments and request for a hearing should state: (1) The name, address, and telephone number of the person making the comment or request, and (2) the nature of the person's interest in the exemption and the manner in which the person would be adversely affected by the exemption. A request for a hearing must also state the issues to be addressed and include a general description of the evidence to be presented at the hearing. A request for a hearing must also state the issues to be addressed and include a general description of the evidence to be presented at the hearing.

ADDRESSES: All written comments and request for a hearing (at least three copies) should be sent to the Pension and Welfare Benefits Administration, Office of Exemption Determinations, room N–5649, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210. Attention: Application No. stated in each Notice of Proposed Exemption. The applications for exemption and the comments received will be available for public inspection in the Public Documents Room of Pension and Welfare Benefits Administration, U.S. Department of Labor, room N–5507, 200 Constitution Avenue, NW., Washington, DC 20210.

Notice to Interested Persons

Notice of the proposed exemptions will be provided to all interested persons in the manner agreed upon by the applicant and the Department within 15 days of the date of publication in the **Federal Register**. Such notice shall include a copy of the notice of proposed exemption as published in the **Federal Register** and shall inform interested persons of their right to comment and to request a hearing (where appropriate).

SUPPLEMENTARY INFORMATION: The proposed exemptions were requested in applications filed pursuant to section 408(a) of the Act and/or section 4975(c)(2) of the Code, and in accordance with procedures set forth in 29 CFR part 2570, subpart B (55 FR 32836, 32847, August 10, 1990). Effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978) transferred the authority of the Secretary of the Treasury to issue exemptions of the type requested to the Secretary of Labor. Therefore, these notices of proposed exemption are issued solely by the Department.

The applications contain representations with regard to the proposed exemptions which are summarized below. Interested persons are referred to the applications on file with the Department for a complete statement of the facts and representations.

Otologic Medical Services, P.C. Profit Sharing Plan (the Plan) Located in Iowa City, IA; Proposed Exemption

[Application No. D–8769]

The Department is considering granting an exemption under the authority of section 4975(c)(2) of the Code and in accordance with the procedures set forth in 29 CFR part 2570, subpart B (55 FR 32836, August 10, 1990). If the exemption is granted, the sanctions resulting from the application of section 4975 of the Code, by reason of sections 4975(c)(1) (A) through (E) of the Code, shall not apply to the proposed purchase, by the account of Dr. Guy E. McFarland (the Account) under the Plan, of a 50 percent undivided interest (the Interest) in a parcel of undeveloped real property (the Property) from Dr. Guy E. McFarland and his wife Bonita, joint owners of the Interest and disqualified persons with respect to the Plan, provided the purchase price does not exceed the fair market value of the Interest on the date of the purchase.

Summary of Facts and Representatives

1. The Plan is a profit-sharing plan which permits each Plan participant to control the investment of the Account. The Plan has approximately 11 participants, including Dr. McFarland

who is a 33⅓ percent owner of the corporation maintaining the Plan. As of August 1, 1990, the Account's balance amounted to approximately $1,600,000.

2. In July of 1989, Dr. McFarland purchased the Property which is located at Section 36 NewPort Township in Johnson County, Iowa, from an unrelated party. Subsequently, Dr. McFarland sold a 50% undivided interest in the Property to Dr. Neal N. Lewellyn, an unrelated party. The Property includes cropland as well as grazing and wooded areas.

3. Michael J. Cilek (Mr. Cilek), an independent real estate appraiser properly qualified and licensed to conduct appraisals in the State of Iowa, has determined by applying appraisal principles to comparable property values, that the fair market value of the Interest, as of September 12, 1991, was $279,300. Mr. Cilek states that less than one percent of his yearly gross income has become derived from his business with Dr. McFarland.

4. The applicant represents that the purchase of the Interest would serve to diversify the assets of the Account. The applicant further represents that he believes the Property (and the Interest therein) offer significant potential for appreciation. It is proposed that the Account will pay a lump sum of cash for the Interest on the purchase date. The applicant states that before the purchase is consummated, an updated appraisal will be performed to determine the fair market value of the Interest as of that date. In addition, the applicant represents that the Account will not pay any commissions or other expenses to effect the proposed purchase.

5. In summary, the applicant represents that the proposed transaction satisfies the exemption criteria set forth in section 408(a) of the Act because: (a) The proposed purchase price will be equal to the fair market value of the Interest as of the purchase date; (b) the proposed purchase will not exceed 25 percent of the value of the Account and (c) the only Plan participant affected by the proposed purchase will be Dr. McFarland, and he desires to consummate the purchase.

Notice to Interested Persons: Since the only Plan assets involved in the proposed transaction are those in the Account and since Dr. McFarland is the only participant affected by the proposed transaction, it has been determined that there is no need to distribute the notice of proposed exemption to interested persons. Comments and hearing requests on the proposed exemption are due 30 days after the date of publication of this notice in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Mr. Eric Berger of the Department, telephone (202) 523–8971. (This is not a toll-free number.)

River Oaks & Trust Company Group Trust for Qualified Trusts of Employee Benefits Plans (ROTC Group Trust) Located in Houston, TX; Proposed Exemption

[Application Nos. D–8738, D–8741 and D–8742]

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth 29 CFR part 2570, subpart B (55 FR 32836, 32847, August 10, 1990). If the exemption is granted, the restrictions of sections 406(a) and 406(b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of sections 4975(c)(1)(A) through (E) of the Code, shall not apply to the proposed series of cash loans not to exceed $811,703, made from time to time, (the Loans) to the ROTC Group Trust by the River Oaks Trust Company (ROTC), a party in interest with respect to the qualified employee benefit plans (the Plans) that participate in the ROTC Group Trust, provided (1) no collateral is required of, and no interest charges or other expenses are incurred by, the ROTC Group Trust or the Plans; (2) the proceeds of the Loans are used only to honor written requests of the Plans for withdrawals from the ROTC pooled investment funds which have invested in Sentinel Real Estate Fund (SRE Fund); (3) the Loans are in lieu of the periodic redemptions that have been suspended by the SRE Fund; (4) repayment of the Loans is restricted to cash obtained from the SRE Fund by the ROTC Group Trust pursuant to redemption requests; and (5) funds received from the SRE Fund in excess of the amount of the Loans will be retained by the ROTC Group Trust and then allocated to the Plans that participate in the ROTC Group Trust's investments in the SRE Fund.

Summary of Facts and Representations

1. The applicant is ROTC, a Texas chartered trust company located in Houston, Texas. ROTC does not function as a bank and therefore, does not accept deposits. It is owned by River Oaks Bancorporation, Inc.,[1] a Delaware corporation organized as a bank holding company under the Bank Holding Company Act 1956, as amended, located in Houston, Texas, and which in turn is owned by Compass Bancshares, Inc., a Texas corporation, organized as a bank holding company under the Bank Holding Company Act of 1956, as amended, located in Houston, Texas. The owner of Compass Bancshares, Inc. is Central Bancshares of the South, Inc., a Delaware corporation located in Birmingham, Alabama, and organized in 1970 as a bank holding company under the Bank Holding Company Act of 1956, as amended.

ROTC, the only affiliate of Compass Bancshares, Inc. with trust powers in the state of Texas, performs as trustee and investment manager in a fiduciary capacity as defined in the Act, through its establishment and operation of the ROTC Group Trust. The ROTC Group Trust maintains eight different collective or pooled investment funds providing a variety of investments for 42 participating Plans. Only three of the eight investment funds of the ROTC Group Trust will be involved in the Loans because of their direct or indirect investments in the SRE Fund. The three investment funds are the ROTC Keogh Balanced Growth Fund (the Keogh Fund), the ROTC Real Estate Fund (the Real Estate Fund), and the ROTC Corporate Balanced Fund [2] (the Corporate Balanced Fund; collectively, the Funds).

2. The SRE Fund is a group trust located in New York, N.Y. and formed for the purpose of providing pension and profit sharing trusts which are exempt from federal income taxation with a vehicle for pooling a portion of their funds for investment in real estate and interests in real estate. The SRE Fund is not related to ROTC or any affiliates of ROTC. It commenced operations on October 1, 1976, pursuant to the terms of a Trust Agreement and is subject to the applicable provisions of the Act. At the time of its commencement, the SRE Fund entered into an Investment Management Agreement with Sentinel Real Estate Corporation (SREC). Under the terms of this agreement, SREC is responsible for the acquisition, management, and disposition of all investments of the SRE Fund, as well as performance of the day-to-day administrative operations. Beneficial interests held by investors in the SRE Fund are designated as units (Units) and

[1] River Oaks Bancorporation, Inc. also owns River Oaks Bank located in Houston, Texas.

[2] The Corporate Balanced Fund has indirectly invested in the SRE Fund by its investments in the Real Estate Fund which is in turn invested in the SRE Fund.

are marketed to qualified employee benefit plans and their tax exempt trusts. The number of Units each investor is issued is determined by dividing the value of the funds invested by an investor in the SRE Fund by the Unit net asset value of the SRE Fund as of its most recent quarterly valuation date.

In accordance with the terms of the SRE Fund, investors may only dispose of their Units in the SRE Fund by requesting in writing a redemption from the SRE Fund of all or a portion of their respective Units. Prior to March 1990, requests for redemption were completed in 30 days after receiving the request by the SRE Fund. This prompt reaction to redemption requests changed during 1990. During March, June, and September 1990, ROTC Group Trust requested redemption of its entire investment in the SRE Fund. On each occasion only a partial, minimal redemption was made by the SRE Fund. Subsequently to the partial redemptions, the SRE Fund notified ROTC Group Trust that no additional Units would be redeemed because of the lack of liquidity in the real estate markets. The SRE Fund declared a moratorium in 1990 on the redemption of its Units for an indefinite period.

As of June 30, 1991, the applicant represents that the current market value of the 2.89 Units held by the Keogh Fund was $176,896 and the current market value of the 10.36 Units held by the Real Estate Fund was $634,807. The Corporate Balanced Fund, which offers a balanced investment opportunity for small Plans by investing its assets in the other funds of the ROTC Group Trust, is not directly invested in Units of the SRE Fund. Units in the SRE Fund held by the Real Estate Fund also indirectly represent assets invested by the Corporate Balanced Fund in the Real Estate Fund.

3. The applicant seeks an exemption from the prohibited transaction provisions of the Act to permit it to make the Loans from time to time to the ROTC Group Trust in amount not to exceed $811,703, which represents the fair market value of the SRE Fund Units, as of June 30, 1991, held by the ROTC Group Trust. The Loans will vary according to the liquidity needs of the Plans and will be activated only in response to written requests for redemption from the respective, independent fiduciaries of the Plans invested in the Funds holding directly or indirectly Units of the SRE Fund. All of the Loans will be interest-free and uncollateralized. The Loans will be in the form of written notes with repayment of principal generated only from proceeds realized from the redemption of Units in the SRE Fund by the ROTC Group Trust. The value of redemptions will be determined by the net asset value of the Units of the SRE Fund, which will continue to be valued quarterly, and thus the value of the Units held by the ROTC Group Trust will fluctuate. Any deficiencies in the SRE Fund redemptions will be compensated by the Loans from ROTC. The applicant represents that if the redemption of the Units in the SRE Fund produces funds in excess of the Loans, such excess funds will be retained by the ROTC Group Trust and allocated to the respective Plans invested in the Funds holding Units of the SRE Fund on the date of the distribution of the excess funds by the SRE Fund.

If the redemption of the Units in the SRE Fund does not produce sufficient funds to repay the Loans, ROTC will waive the repayment of the Loans. ROTC will absorb any losses and not look to any other source for repayment Also, the applicant represents that the Loans will not cause the Plans to incur any costs or expenses.

4. The applicant represents that the sole purpose of the Loans is to protect the interests of the participants and beneficiaries of the Plans by providing liquidity to the Plans that are invested in the Funds of the ROTC Group Trust which are invested in the illiquid SRE Fund. The Loans will enable the Plans to pay benefits and defray reasonable expenses of administering the Plans, as well as diversify investments of the Plans. The independent fiduciaries of the Plans will act independently of the ROTC Group Trust when activating the Loans by their respective redemption requests. The applicant also represents that the decisions for redemption by the independent fiduciaries of the Plans will be the sole and controlling basis for making the Loans.

5. In summary, the applicant represents that the proposed transaction satisfies the criteria of section 408(a) of the Act for the following reasons (a) the Loans will be evidenced by written instruments with no provision for the payment of interest; (b) the proposed transactions protects the Plans and their participants and beneficiaries from the lack of liquidity of the SRE Fund; (c) repayment of the Loans is limited to the cash proceeds received from the redemption of Units issued by the SRE Fund and no other assets of the Funds will be affected or used for repayment; and (d) upon redemption of Units issued by the SRE Fund, any proceeds received in excess of the Loans will be allocated to the Plans that are then invested in the Funds of the ROTC Group Trust on the date of such excess funds are received.

FOR FURTHER INFORMATION CONTACT: Mr. C.E. Beaver of the Department, telephone (202) 523–8881. (This is not a toll-free number.)

Pilgrim's Pride Retirement Savings Plan (the Plan) Located in Pittsburg, TX; Proposed Exemption

[Application No. D–8819]

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in 29 CFR 2570, subpart B (55 FR 32836, 32847, August 10, 1990). If the exemption is granted the restrictions of section 406(a) and 406 (b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code shall not apply to: (1) The proposed cash sale of two parcels (herein identified as Parcels #10 and #11) of improved and unimproved real property by the Plan to Pilgrim's Pride Corporation (the Employer), a party in interest with respect to the Plan; and (2) the proposed cash sale of nine other parcels (herein identified as Parcels #1 through #9) of improved and unimproved real property by the Plan to the Employer; provided the following terms and conditions are met: (a) The terms of the sales are not less favorable to the Plan than similar terms negotiated at arm's length between unrelated third parties; (b) the aggregate sales price of Parcels #10 and #11, as determined by an independent, qualified appraiser, on the date of the sale; and (c) the aggregate sales price of Parcels #1 through #9 is the greater of $559,900 or the sum of the fair market values of Parcels #1 through #9, as determined by an independent, qualified appraiser, on the date of the sale.[3]

Summary of Facts and Representations

1. The Employer is a corporation organized under the laws of the State of Delaware but has its principal place of business at 1105 Texas Ave., Pittsburg, Texas. The Employer is engaged in the breeding, feeding, and raising of chickens and in the processing, packaging, and selling, in the wholesale and retail markets, of commercially prepared cooked and uncooked chicken and of chicken byproducts.

[3] For purposes of this proposed exemption references to specific provisions of Title I of the Act, unless otherwise specified, refer also to the corresponding provisions of the Code.

2. The Plan is a tax qualified profit sharing plan, pursuant to section 401(a) of the Code and is the successor to a profit sharing plan established on January 1, 1969, for employees of Netex Poultry Company, Inc., the predecessor of the Employer. As of June 30, 1990, the Plan had an estimated 6,184 participants and assets totaling $12,384,560.

The assets of the Plan are held in a tax exempt trust (the Trust), pursuant to section 501(a) of the Code. The current trustees of the Trust (the Trustees) are Lonnie A. Pilgrim (Mr. Pilgrim), Clifford E. Butler (Mr. Butler), and Robert L. Hendrix (Mr. Hendrix). Charles L. Black served as a former trustee of the Trust. Each of the current Trustees are employees, officers, and shareholders of the Employer. Mr. Pilgrim owns approximately 79% of the outstanding shares of the Employer and is its chief executive officer. Mr. Butler and Mr. Hendrix together own less than 1% of the outstanding shares of the Employer.

3. It is represented that the Trust on behalf of the Plan owns eleven (11) parcels (the Parcels) of improved and unimproved real property. The Parcels were purchased by the Plan from unrelated third party sellers on various dates from February 26, 1974 through June 1, 1982. The aggregate purchase price paid by the Plan for the Parcels was approximately $376,744. It is represented that the Parcels were purchased as investments to be held indefinitely by the Plan. All of the Parcels are located either in the agricultural area surrounding the Employer's principal place of business in Pittsburg, Texas or near the Employer's facilities in Mt. Pleasant, Texas [4] The aggregate value of the Parcels constitutes approximately 4.6% of the assets of the Plan.

4. Parcels #1 through #5 are located in Camp County, Texas. Parcels #1 and #2 are described as unimproved rural farm land, consisting of 159.38 acres and 65.4 acres, respectively. Parcel #3 contains 30 acres and is improved with a residential building. It is represented that the quality and condition of the existing structures on Parcels #4 and #5 add no contributory value and that these parcels are considered as unimproved land consisting of 31.7 acres and 55 acres, respectively.

The Employer has taken certain actions with respect to Parcels #1 through #5. It is represented that some or all of these Parcels were fertilized, mowed, cleared of brush and trash, and improved with repaired or new fences. In addition, the Employer paid the taxes, the insurance premiums, and other expenses on these Parcels. It is represented that income to offset a portion of these expenses has been generated from silage crops grown on Parcels #1, #3, #4, and #5 and from rental of the residence on Parcel #3. The Employer maintains that it has not otherwise made use of or benefited from its actions with respect to Parcels #1 through #5.

5. Parcels #6 through #11 are located in Mt. Pleasant, Titus County, Texas. Parcels #6, #7, and #8 are zoned for heavy manufacturing. Parcel #6 is improved with a concrete tile shop building and asphalt paving. Parcel #7 is improved with a steel frame metal building and asphalt paving. Parcel #8 is improved with asphalt paving only. Parcels #9, #10, and #11 are zoned single family residential. Parcel #9 is improved with a storm drain and concrete paving. Parcel #10 is improved with a chain link fence. Parcel #11 is unimproved.

It is represented that since the Plan acquired them, the Employer or its predecessor have occupied Parcels #6, #7, #9, #10, and #11 under the terms of annual or month to month written leases executed between the Plan and the Employer or its predecessor. In the case of Parcel #8, the Employer has occupied and used the land as a parking lot for trucks, but no formal written lease has been found to document the arrangement. It is represented that the Employer pays an aggregate monthly rental of $427.14 for using or leasing Parcels #6 through #11.[5]

6. It is represented that effective July 1, 1991, the Employer amended the Plan in order to provide for participant directed investments, pursuant to section 404(c) of the Act and the proposed regulations (56 FR 10724, March 13, 1991). The Employer has selected several mutual fund options from which participants may choose. In order to fully implement the change to participant directed accounts, it is represented that all assets under the Plan must be liquidated and invested in the mutual fund options. Until this can be accomplished, the Plan will incur administrative expense in separately accounting for the Parcels.

In order to avoid this expense to the Plan, the Employer proposes to purchase Parcels #1 through #9 from the Plan for an aggregate cash price which is the greater of $559,900 or the sum of the fair market values of the Parcels, as determined by an independent, qualified appraiser, on the date of sale. It is represented that with the exception of Parcels #10 and #11 which were appraised by independent qualified appraisers (see, paragraph no. 7 below) at $3,000 and $2,700, respectively, the value of all of the Parcels has appreciated over time. The Employer represents that with respect to Parcels #10 and #11, the Plan will be made whole. In this regard, the Employer will pay in cash the greater of $14,308, the Plan's total cost in acquiring Parcels #10 and #11 ($7,500 and $6,808, respectively) or the sum of the fair market values of Parcels #10 and #11, as determined by an independent, qualified appraiser, on the date of the sale.

In selling the Parcels to the Employer, the Plan would also avoid the likelihood of a third party sale at a discount and/or the risk of providing financing for any sale of the Parcels to an outside purchaser. In addition, it is represented that the liquidity of the Plan would be enhanced by the sale of the Parcels to the Employer. It is represented that the Employer will bear the costs and expenses of obtaining the exemption and of notifying interested persons.

7. Bob G. Derryberry, ARA, ASA, and William H. Manning, MAI, independent, qualified third party appraisers with Bob Derryberry and Associates, in Garland, Texas inspected each of the Parcels and prepared an appraisal report dated June 24, 1991. In this appraisal report, they estimated the value of the Parcels, as unencumbered by any existing leases with the Employer. The appraisers represent that the fair market value of the Parcels, as of May 16, 1991, was $565,000.

Because of proximity of the Parcels to the Employer's facilities and the applicability of the Parcels in the operation of the Employer's business, the appraisers were asked to address whether the Parcels have a higher value to the Employer than they would to an unrelated third party purchaser. Accordingly, the June appraisal report was supplemented by information

[4] The Department notes that the Trustees' decisions to acquire and hold the Parcels are governed by the fiduciary responsibility requirements of Part 4, Subtitle B, Title I of the Act. The Department, herein, is not proposing relief for any violation of the provisions of Part 4, Subtitle B, Title I of the Act which may have arisen, as a result the Plan's investment in, or continued holding of, the Parcels.

[5] The Employer recognizes that the leasing and use of the Parcels may have constituted prohibited transactions under the Act. As a result, the Employer represents that within 60 days of the date of the grant of this proposed exemption, they will file the FORM 5330 with the Internal Revenue Service, and will pay any applicable excise tax deemed to be due and owing with respect to such leasing and use. The Employer will also pay to the Plan the excess, if any, of the fair market rental, as determined by an independent, qualified appraiser, with respect to such leasing and use over the actual amount paid to the Plan, plus interest.

provided in a letter from the appraisers, dated October 21, 1991. In this letter, the appraisers represent that the appraised value of the Parcels, in this case, reflects the same fair market value, regardless of whether the purchaser is the Employer or an unrelated third party.

8. In summary, the applicant represents that the proposed transaction satisfies the statutory criteria for an exemption under section 408(a) of the Act because:

(a) The sale of the Parcels will be a one time transaction for cash;

(b) The Plan will avoid incurring expenses caused by the necessity of separately accounting for the Parcels in the context of a participant directed account plan, pursuant to section 404(c) of the Act;

(c) The Plan will avoid the likelihood of sale at a discount to a third party, and/or the risk of providing financing for such a purchase;

(d) The aggregate sales price for Parcels #10 and #11 will be the greater of $14,303, the Plan's total cost in acquiring Parcels #10 and #11, or the sum of the fair market values of Parcels #10 and #11, as determined by an independent, qualified appraiser, on the date of the sale;

(e) The aggregate sales price for Parcels #1 through #9 will be the greater of $559,900 or the sum of the fair market values of Parcels #1 through #9, as determined by an independent, qualified appraiser, on the date of the sale; and

(f) The liquidity of the Plan will be enhanced by the sale.

FOR FURTHER INFORMATION CONTACT: Angelena C. Le Blanc of the Department, telephone (202) 523–8883. (This is not a toll-free number.)

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption under section 408(a) of the Act and/or section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest of disqualified person from certain other provisions of the Act and/or the Code, including any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of section 404 of the Act, which among other things require a fiduciary to discharge his duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(b) of the act; nor does it affect the requirement of section 401(a) of the Code that the plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries;

(2) Before an exemption may be granted under section 408(a) of the Act and/or section 4975(c)(2) of the Code, the Department must find that the exemption is administratively feasible, in the interests of the plan and of its participants and beneficiaries and protective of the rights of participants and beneficiaries of the plan; and

(3) The proposed exemptions, if granted, will be supplemental to, and not in derogation of, any other provisions of the Act and/or the Code, involving statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of whether the transaction is in fact a prohibited transaction.

(4) The proposed exemptions, if granted, will be subject to the express condition that the material facts and representations contained in each application are true and complete, and that each application accurately describes all material terms of the transaction which is the subject of the exemption.

Signed at Washington, DC, this 19th day of December 1991.

Ivan Strasfeld,

Director of Exemption Determinations, Pension and Welfare Benefits Administration, U.S. Department of Labor.

[FR Doc. 91–30680 Filed 12–23–91; 8:45 am]

BILLING CODE 4510–29–M

NUCLEAR REGULATORY COMMISSION

Licensing Support System Advisory Review Panel; Renewal

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Notice of renewal of the Licensing Support System Advisory Review Panel (LSSARP) for a period of two years.

SUPPLEMENTARY INFORMATION: The Nuclear Regulatory Commission has determined that renewal of the charter for the LSSARP for the two year period commencing December 18, 1991 is in the public interest in connection with duties imposed on the Commission by law. This action is being taken in accordance with the Federal Advisory Committee Act after consultation with the Committee Management Secretariat, General Services Administration.

The purpose of the LSSARP is to provide advice to (1) the Department of Energy on the fundamental issues of design and development of an electronic information management system to be used to store and retrieve documents relating to the licensing of a geologic repository for the disposal of high-level radioactive waste, and (2) the Nuclear Regulatory Commission on the operation and maintenance of the system. This electronic information management system is known as the Licensing Support System (LSS).

Membership on the Panel is drawn from those interests that will be affected by the use of the LSS, including the Department of Energy, the NRC, the State of Nevada, Tribal interests, affected units of local governments in Nevada, and the nuclear industry. Federal agencies with expertise and experience in electronic information management systems also participate on the Panel.

Further information regarding the LSS Advisory Review Panel may be obtained from Marilee Rood, Office of the LSS Administrator, NRC, Washington, DC 20555; telephone: (301) 504–4003.

Dated: December 18, 1991.

John C. Hoyle,

Advisory Committee Management Officer.

[FR Doc. 91–30661 Filed 12–23–91; 8:45 am]

BILLING CODE 7590–01–M

Advisory Committee on Reactor Safeguards; Subcommittee on Improved Light Water Reactors; Meeting

The Subcommittee on Improved Light Water Reactors will hold a meeting on January 22, 1992, room P–110, 7920 Norfolk Avenue, Bethesda, MD.

The entire meeting will be open to public attendance.

The agenda for the subject meeting shall be as follows:

Wednesday, January 22, 1992—8:30 a.m. Until the Conclusion of Business

The Subcommittee will review SECY–91–300 and the related draft safety evaluation report for chapter 10 of the EPRI's Requirements Document for evolutionary designs.

Oral statements may be presented by members of the public with the concurrence of the Subcommittee Chairman; written statements will be accepted and made available to the Committee. Recordings will be permitted only during those sessions of the meeting when a transcript is being kept, and questions may be asked only by members of the Subcommittee, its consultants, and staff. Persons desiring to make oral statements should notify

the ACRS staff member named below as far in advance as is practicable so that appropriate arrangements can be made.

During the initial portion of the meeting, the Subcommittee, along with any of its consultants who may be present, may exchange preliminary views regarding matters to be considered during the balance of the meeting.

The Subcommittee will hear presentations by the hold discussions with representatives of the NRC staff, their consultants, and other interested persons regarding this review.

Further information regarding topics to be discussed, the scheduling of sessions open to the public, whether the meeting has been cancelled or rescheduled, the Chairman's ruling on requests for the opportunity to present oral statements and the time allotted therefor can be obtained by a prepaid telephone call to the cognizant ACRS staff member, Dr. Medhat El-Zeftawy (telephone 301/492–9901) between 7:30 a.m. and 4:15 p.m. Persons planning to attend this meeting are urged to contact the above named individual one or two days before the scheduled meeting to be advised of any changes in schedule, etc., that may have occurred.

Dated: December 18, 1991.

Gary R. Quittschreiber,

Chief, Nuclear Reactors Branch.

[FR Doc. 91–30662 Filed 12–23–91; 8:45 am]

BILLING CODE 7590–01–M

Advisory Committee on Reactor Safeguards, Subcommittee on Advanced Boiling Water Reactors; Meeting

The Subcommittee on Advanced Boiling Water Reactors will hold a meeting on January 23-24, 1992, room P–110, 7920 Norfolk Avenue, Bethesda, MD.

The entire meeting will be open to public attendance.

The agenda for the subject meeting shall be as follows:

Thursday, January 23, 1992—8:30 a.m. until the conclusion of business.

Friday, January 24, 1992—8:30 a.m. until the conclusion of business.

The Subcommittee will review SECY–91–294 and SECY–91–309 addressing two drafting safety evaluation reports related to different chapters of the GE/Standard Safety Analysis Report for the ABWR design and other related issues.

Oral statements may be presented by members of the public with the concurrence of the Subcommittee Chairman; written statements will be accepted and made available to the Committee. Recordings will be permitted only during those sessions of the meeting when a transcript is being kept, and questions may be asked only by members of the Subcommittee, its consultants, and staff. Persons desiring to make oral statements should notify the ACRS staff member named below as far in advance as is practicable so that appropriate arrangements can be made. During the initial portion of the meeting, the Subcommittee, along with any of their consultants who may be present, may exchange preliminary views regarding matters to be considered during the balance of the meeting.

The Subcommittee will then hear presentations by and hold discussions with representatives of the General Electric, NRC staff, their consultants, and other interested persons regarding this review.

Further information regarding topics to be discussed, the scheduling of sessions open to the public, whether the meeting has been canceled or rescheduled, the Chairman's ruling on requests for the opportunity to present oral statements and the time allotted therefor can be obtained by a prepaid telephone call to the cognizant ACRS staff member, Dr. Medhat M. El-Zeftawy (telephone 301/492–9901) between 7:30 a.m. and 4:15 p.m. Persons planning to attend this meeting are urged to contact the above named individual one or two days before the scheduled meeting to be advised of any changes in schedule, etc., that may have occurred.

Dated: December 18, 1991.

Gary R. Quittschreiber,

Chief, Nuclear Reactors Branch.

[FR Doc. 91–30698 Filed 12–23–91; 8:45 am]

BILLING CODE 7590–01–M

State of Maine: Staff Assessment of Proposed Agreement Between the Nuclear Regulatory Commission and the State of Maine

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of Proposed Agreement with the State of Maine.

SUMMARY: The U.S. Nuclear Regulatory Commission is publishing for public comment the NRC staff assessment of a proposed agreement received from the Governor of the State of Maine for the assumption of certain of the Commission's regulatory authority pursuant to section 274 of the Atomic Energy Act of 1954, as amended. Comments are requested on the public health and safety aspects of the proposal.

Exemptions from the Commission's regulatory authority, which would implement this proposed agreement, have been published in the **Federal Register** and codified as part 150 of the Commission's regulations in Title 10 of the Code of Federal Regulations.

DATES: Comments must be received on or before January 2, 1992.

ADDRESSES: Submit comments to the Chief, Regulatory Publications Branch, Division of Freedom of Information and Publications Services, Office of Administration, Washington, DC 20555. Comments may also be delivered to 7920 Norfolk Avenue, Bethesda, Maryland from 7:30 a.m. to 4:15 p.m. Monday through Friday. Copies of comments received by NRC may be examined at the NRC Public Document Room, 2120 L Street, NW., (Lower Level), Washington, DC. A copy of the proposed agreement, program narrative, including the referenced appendices, applicable State legislation and Maine regulations, is available for public inspection in the NRC's Public Document Room, 2120 L Street, NW., (Lower Level), Washington, DC, telephone: (202) 634–3273.

FOR FURTHER INFORMATION CONTACT: Kathleen N. Schneider, State Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone: 301–492–0320.

SUPPLEMENTARY INFORMATION: Assessment of Proposed Maine Program to Regulate Certain Radioactive Materials pursuant to section 274 of the Atomic Energy Act of 1954, as amended (the Act).

The Commission has received a proposal from the Governor of Maine for the State to enter into an agreement with the NRC whereby the NRC would relinquish and the State would assume certain regulatory authority pursuant to section 274 of the Act.

Section 274e of the Act requires that the terms of the proposed agreement be published for public comment once each week for four consecutive weeks. Accordingly, this notice will be published four times in the **Federal Register**.

I. Background

A. Section 274 of the Act provides a mechanism whereby the NRC may transfer to the States certain regulatory authority over agreement materials [1]

[1] A. Byproduct materials as defined in 11e.(1)
B. Byproduct materials as defined in 11e.(2)
C. Source materials; and
D. Special nuclear materials in quantities not sufficient to form a critical mass

when a State desires to assume this authority and the Governor certifies that the State has an adequate regulatory program, and when the Commission finds that the State's program is compatible with that of the NRC and is adequate to protect the public health and safety. Section 274g directs the Commission to cooperate with the States in the formulation of standards for protection against radiation hazards to assure that State and Commission programs for radiation protection will be coordinated and compatible. Further, section 274j provides that the Commission shall periodically review such agreements and actions taken by the States under the agreements to ensure compliance with the provisions of this section.

B. In a letter dated March 5, 1990, Governor John P. McKernan, Jr. of the State of Maine requested that the Commission enter into an agreement with the State pursuant to section 274 of the Act. The Governor certified that the State of Maine has a program for control of radiation hazards which is adequate to protect the public health and safety with respect to the materials within the State covered by the proposed agreement, and that the State of Maine desires to assume regulatory responsibility for such materials. The text of the proposed agreement is shown in Appendix A to this document.

The specific authority requested is for (1) byproduct material as defined in section 11e.(1) of the Act, (2) source material, and (3) special nuclear material in quantities not sufficient to form a critical mass. The State does not wish to assume authority over (1) land disposal of source, byproduct and special nuclear material received from other persons; and (2) uranium recovery activities (byproduct material as defined in section 11e(2)). The State, however, reserves the right to apply at a future date to NRC for an amended agreement to assume authority in these areas. The nine articles of the proposed agreement—

Lists the materials covered by the agreement.

Lists the Commission's continued authority and responsibility for certain activities.

Allows for future amendment of the agreement.

Allows for certain regulatory changes by the Commission.

References the continued authority of the Commission for common defense and security for safeguard purposes.

Pledge the best efforts of the Commission and the State to achieve coordinated and compatible programs.

Recognizes reciprocity of licenses issued by the respective agencies.

Sets forth criteria for termination or suspension of the agreement.

Specifies the effective date of the agreement.

C. Maine Radiation Protection Act, sections 671 through 690, the enabling statute for the Maine Department of Human Services, authorizes the Department to issue licenses to, and perform inspections of, users of radioactive materials under the proposed agreement and otherwise carry out a total radiation control program. Maine regulations for radiation protection were adopted on January 1, 1986, with revisions dated January 1, 1988 and December 1, 1990, under authority of the enabling statute and provide standards, licensing, inspection, enforcement and administrative procedures for agreement and non-agreement materials. In addition, editorial revisions recommended by NRC are presently under consideration in Maine and are expected to be finalized in November 1991. Pursuant to Maine's regulations, section C.19, the regulations will apply to agreement materials on the effective date of the agreement. In addition to the material covered under the proposed agreement, the regulations provide for the State to license and inspect users of naturally-occurring and accelerator-produced radioactive materials.

D. The NRC staff assessment finds the proposed Maine program will provide adequately for public health and safety.

II. NRC Staff Assessment of the Proposed Maine Program for Control of Agreement Materials

Reference: Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement.[2]

Objectives

1. *Protection.* A State regulatory program shall be designed to protect the health and safety of the people against radiation hazards.

Based upon the analysis of the State's proposed regulatory program, the staff believes the Maine proposed regulatory program for agreement materials is adequately designed to protect the health and safety of the public against radiation hazards.

Reference: Maine Program Statement, Application for Agreement State Status.

[2] NRC Statement of Policy published in the Federal Register January 23, 1981 (46 FR 7540–7546), a correction was published July 16, 1981 (46 FR 36969) and a revision of Criterion 9 published in the Federal Register July 21, 1983 (48 FR 33376).

Radiation Protection Standards

2. *Standards.* The State regulatory program shall adopt a set of standards for protection against radiation which shall apply to byproduct, source and special nuclear materials in quantities not sufficient to form a critical mass.

Statutory authority to formulate and promulgate rules for controlling exposure to sources of radiation is contained in the enabling statute. In accordance with that authority, the State adopted radiation control regulations on January 1, 1986, and with revisions dated January 1, 1988, and December 1, 1990, which include radiation protection standards which would apply to byproduct, source and special nuclear materials in quantities not sufficient to form a critical mass upon the effective date of an agreement between the State and the Commission pursuant to Section 274b of the Atomic Energy Act of 1954, as amended. In addition, editorial revisions recommended by NRC are presently under consideration by the State and are expected to be finalized in November 1991.

Reference: State of Maine Rules Relating to Radiation Protection Parts A, B, C, D, E, G, J, K, L, Letter dated October 15, 1991.

3. *Uniformity in Radiation Standards.* It is important to strive for uniformity in technical definitions and terminology, particularly as related to such things as units of measurement and radiation dose. There shall be uniformity on maximum permissible doses and levels of radiation and concentrations of radioactivity, as fixed by 10 CFR part 20 of the NRC regulations based on officially approved radiation protection guides.

Technical definitions and terminology contained in the Maine Radiation Control Regulations including those related to units of measurement and radiation doses are uniform with those contained in 10 CFR part 20.

Reference: State of Maine Rules Relating to Radiation Protection Sections A.2, D.2, E.3, G.2, K.3, L.2.

4. *Total Occupational Radiation Exposure.* The regulatory authority shall consider the total occupational radiation exposure of individuals, including that from sources which are not regulated by it.

The Maine regulations cover all sources of radiation within the State's jurisdiction and provide for consideration of the total radiation exposure of individuals from all sources of radiation in the possession of a licensee or registrant.

Reference: State of Maine Rules Relating to Radiation Protection Sections D.2 to D.7.

5. *Surveys, Monitoring.* Appropriate surveys and personnel monitoring under the close supervision of technically competent people are essential in achieving radiological protection and shall be made in determining compliance with safety regulations.

The Maine requirements for surveys to evaluate potential exposures from sources of radiation and the personnel monitoring requirements are uniform with those contained in 10 CFR part 20.

References: State of Maine Rules Relating to Radiation Protection Sections D.9, D.10 and D.15.

6. *Labels, Signs, Symbols.* It is desirable to achieve uniformity in labels, signs, and symbols, and the posting thereof. However, it is essential that there be uniformity in labels, signs, and symbols affixed to radioactive products which are transferred from person to person.

The prescribed radiation labels, signs and symbols are uniform with those contained in 10 CFR parts 20, 30 thru 32 and 34. The Maine posting requirements are also uniform with those of 10 CFR part 20.

References: State of Maine Rules Relating to Radiation Protection Sections C.6.E, C.6.F, C.11.D, D.11 and D.12.

7. *Instruction.* Persons working in or frequenting restricted areas shall be instructed with respect to the health risks associated with exposure to radioactive materials and in precautions to minimize exposure. Workers shall have the right to request regulatory authority inspections as per 10 CFR 19.16 and to be represented during inspections as specified in 10 CFR 19.14.

The Maine regulations contain requirements for instructions and notices to workers that are uniform with those of 10 CFR part 19.

Reference: State of Maine Rules Relating to Radiation Protection Section J.

8. *Storage.* Licensed radioactive material in storage shall be secured against unauthorized removal.

The Maine regulations contain a requirement for security of stored radioactive material.

Reference: State of Maine Rules Relating to Radiation Protection Section D.14.

9. *Radioactive Waste Disposal.*

(a) Waste disposal by material users. The standards for the disposal of radioactive materials into the air, water and sewer, and burial in the soil shall be in accordance with 10 CFR part 20. Holders of radioactive material desiring to release or dispose of quantities or concentrations of radioactive materials in excess of prescribed limits shall be required to obtain special permission from the appropriate regulatory authority.

Requirements for transfer of waste for the purpose of ultimate disposal at a land disposal facility (waste transfer and manifest system) shall be in accordance with 10 CFR part 20.

The waste disposal standards shall include a waste classification scheme and provisions for waste form, applicable to waste generators, that is equivalent to that contained in 10 CFR part 61.

(b) Land Disposal of waste received from other persons. The State shall promulgate regulations containing licensing requirements for land disposal of radioactive waste received from other persons which are compatible with the applicable technical definitions, performance objectives, technical requirements and applicable supporting sections set forth in 10 CFR part 61. Adequate financial arrangements (under terms established by regulation) shall be required for each waste disposal site licensee to ensure sufficient funds for decontamination, closure and stabilization of a disposal site. In addition, Agreement State financial arrangements for long-term monitoring and maintenance of a specific site must be reviewed and approved by the Commission prior to relieving the site operator of licensed responsibility (Section 151(a)(2), Pub. L. 97–425).

The Maine regulations contain provisions relating to the disposal of radioactive materials into the air, water and sewer and burial in soil which are essentially uniform with those of 10 CFR part 20. Waste transfer and manifest system requirements for transfer of waste for ultimate disposal at a land disposal facility are included in the Maine regulations. The waste disposal requirements include a waste classification scheme and provisions for waste form equivalent to that in 10 CFR part 61.

Maine does not plan on seeking authority for the regulation of land disposal of source, byproduct and special nuclear material received from other persons.

References: State of Maine Rules Relating to Radiation Protection Sections D.7, and D.16 to D.26.

10. *Regulations Governing Shipment of Radioactive Materials.* The State shall to the extent of its jurisdiction promulgate regulations applicable to the shipment of radioactive materials, such regulations to be compatible with those established by the U.S. Department of Transportation and other agencies of the United States whose jurisdiction over interstate shipment of such materials necessarily continues. State regulations regarding transportation of radioactive materials must be compatible with 10 CFR part 71.

The Maine regulations are uniform with those contained in NRC regulations 10 CFR part 71.

References: State of Maine Rules Relating to Radiation Protection Section L.

11. *Records and Reports.* The State regulatory program shall require that holders and users of radioactive materials (a) maintain records covering personnel radiation exposures, radiation surveys, and disposals of materials; (b) keep records of the receipt and transfer of the materials; (c) report significant incidents involving the materials, as prescribed by the regulatory authority; (d) make available upon request of a former employee a report of the employee's exposure to radiation; (e) at request of an employee advise the employee of his or her annual radiation exposure; and (f) inform each employee in writing when the employee has received radiation exposure in excess of the prescribed limits.

The Maine regulations require the following records and reports of the licensees and registrants:

(a) Records covering personnel radiation exposures, radiation surveys, and disposals of materials.
(b) Records of receipt and transfer of materials.
(c) Reports concerning incidents involving radioactive materials.
(d) Reports to former employees of their radiation exposure.
(e) Reports to employees of their annual radiation exposure.
(f) Reports to employees of radiation exposure in excess of prescribed limits.

Reference: State of Maine Rules Relating to Radiation Protection Sections A.4, D.27, D.29, D.30, and J.4.

12. *Additional Requirements and Exemptions.* Consistent with the overall criteria here enumerated and to accommodate special cases and circumstances, the State regulatory authority shall be authorized in individual cases to impose additional requirements to protect health and safety, or to grant necessary exemptions which will not jeopardize health and safety.

The Maine Radiation Control Program is authorized to impose upon any licensee or registrant by rule, regulation, or order such requirements in addition

to those established in the regulations as it deems appropriate or necessary to minimize danger to public health and safety or property.

Reference: State of Maine Rules Relating to Radiation Protection Section A.7.

The Department may also grant such exemptions from the requirements of the regulations as it determines are authorized by law and will not result in undue hazard to public health and safety or property.

Reference: State of Maine Rules Relating to Radiation Protection Section A.3.

Prior Evaluation of Uses of Radioactive Materials

13. *Prior Evaluation of Hazards and Uses, Exceptions.* In the present state of knowledge, it is necessary in regulating the possession and use of byproduct, source and special nuclear materials that the State regulatory authority require the submission of information on, and evaluation of, the potential hazards and the capability of the user or possessor prior to his receipt of the materials. This criterion is subject to certain exceptions and to continuing reappraisal as knowledge and experience in the atomic energy field increase. Frequently there are, and increasingly in the future there may be, categories of materials and uses as to which there is sufficient knowledge to permit possession and use without prior evaluation of the hazards and the capability of the possessor and user. These categories fall into two groups—those materials and uses which may be completely exempt from regulatory controls, and those materials and uses in which sanctions for misuse are maintained without pre-evaluation of the individual possession or use. In authorizing research and development or other activities involving multiple uses of radioactive materials, where an institution has people with extensive training and experience, the State regulatory authority may wish to provide a means for authorizing broad use of materials without evaluating each specific use.

Prior to the issuance of a specific license for the use of radioactive materials, the Maine Radiation Control Program will require the submission of information on, and will make an evaluation of, the potential hazards of such uses, and the capability of the applicant.

References: State of Maine Rules Relating to Radiation Protection Sections C.7 and C.17 and the Maine Program Statement

Provision is made for the issuance of general licenses for byproduct, source and special nuclear materials in situations where prior evaluation of the licensee's qualifications, facilities, equipment and procedures is not required. The regulations grant general licenses under the same circumstances as those under which general licenses are granted in the Commission's regulations.

References: State of Maine Rules Relating to Radiation Protection Sections C.5 and C.6.

The Maine regulations contain provisions for exempting of certain source and other radioactive materials and devices containing radioactive materials. These exemptions, for materials covered by the agreement, are the same as those granted by NRC regulations.

References: State of Maine Rules Relating to Radiation Protection Sections C.2 and C.3.

14. *Evaluation Criteria.* In evaluating a proposal to use radioactive materials, the regulatory authority shall determine the adequacy of the applicant's facilities and safety equipment, his training and experience in the use of the materials for the purpose requested, and his proposed administrative controls. States should develop guidance documents for use by license applicants. This guidance should be consistent with NRC licensing and regulatory guides for various categories of licensed activities.

In evaluating a proposal to use agreement materials, the Maine Radiation Control Program will determine that:

(1) The applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with the regulations in such a manner as to minimize danger to public health and safety or property;

(2) The applicant's proposed equipment, facilities, and procedures are adequate to minimize danger to public health and safety or property; and

(3) The issuance of the license will not be inimical to the health and safety of the public.

Other special requirements for the issuance of specific licenses are contained in the regulations.

References: State of Maine Rules Relating to Radiation Protection Sections C.8 to C.11 and the Maine Program Statement.

15. *Human Use.* The use of radioactive materials and radiation on or in humans shall not be permitted except by properly qualified persons (normally licensed physicians) possessing prescribed minimum experience in the use of radioisotopes or radiation.

The Maine regulations require that the use or radioactive materials (including sealed sources) on or in humans shall be by a physician having substantial experience in the handling and administration of radioactive material and, where applicable, the clinical management of radioactive patients.

Reference: State of Maine Rules Relating to Radiation Protection Sections G.66 to G.76.

Inspection

16. *Purpose, Frequency.* The possession and use of radioactive materials shall be subject to inspection by the regulatory authority and shall be subject to the performance of tests, as required by the regulatory authority. Inspection and testing is conducted to determine and to assist in obtaining compliance with regulatory requirements. Frequency of inspection shall be related directly to the amount and kind of materials and type of operation licensed, and it shall be adequate to insure compliance.

Maine materials licensees will be subject to inspection by Radiation Control Program, Division of Health Engineering, the Department of Human Services. Upon instruction from the Department, licensees shall perform or permit the Department to perform any reasonable test and survey the Department considers appropriate or necessary. The frequency of inspections is dependent upon the type and scope of the licensed activities and will be at least as frequent as inspections of similar licensees by NRC. Generally, inspections will be unannounced.

References: State of Maine Rules Relating to Radiation Protection Sections A.5, A.6, A.7 and J.5.A; Maine Program Statement.

17. *Inspection Compulsory.* Licensees shall be under obligation by law to provide access to inspectors.

Maine regulations state that licensees shall afford the Department, at all reasonable times, opportunity to inspect sources of radiation and the premises and facilities wherein such sources of radiation are used or stored.

Reference: State of Maine Rules Relating to Radiation Protection Section A.5.

18. *Notification of Results of Inspection.* Licensees are entitled to be advised of the results of inspections and to notice as to whether or not they are in compliance.

Following Radiation Control Program inspections, each licensee will be notified in writing of the results of the

inspection. The letters and written notices indicate if the licensee is in compliance and if not, list the areas of noncompliance.

Reference: Maine Program Statement.

Enforcement

19. *Enforcement.* Possession and use of radioactive materials should be amenable to enforcement through legal sanctions, and the regulatory authority shall be equipped or assisted by law with the necessary powers for prompt enforcement. This may include, as appropriate, administrative remedies looking toward issuance of orders requiring affirmative action or suspension or revocation of the right to possess and use materials, and the impounding of materials; the obtaining of injunctive relief; and the imposing of civil or criminal penalties.

The Maine Radiation Control Program is equipped with the necessary powers for prompt enforcement of the regulations. Where conditions exist that create a clear presence of a hazard to the public health that requires immediate action to protect human health and safety, Maine may issue orders to reduce, discontinue or eliminate such conditions. The Radiation Control Program actions may also include impounding of radioactive material, imposition of a civil penalty, revocation of a license, and requesting the State Attorney General to seek injunctions and convictions for criminal violations.

References: State of Maine Rules Relating to Radiation Protection Sections A.7, A.8, A.9, Part B and C.22; Maine Radiation Protection Act Sections 688 and 690; Maine Program Statement.

Personnel

20. *Qualifications of Regulatory and Inspection Personnel.* The regulatory agency shall be staffed with sufficient trained personnel. Prior evaluation of applications for licenses or authorizations and inspections of licensees must be conducted by persons possessing the training and experience relevant to the type and level of radioactivity in the proposed use to be evaluated and inspected. This requires competency to evaluate various potential radiological hazards associated with the many uses of radioactive material and includes concentrations of radioactive materials in air and water, conditions of shielding, the making of radiation measurements, knowledge of radiation instruments—their selection, use, and calibration—laboratory design, contamination control, other general principles and practices of radiation protection, and use of management controls in assuring adherence to safety procedures. In order to evaluate some complex cases, the State regulatory staff may need to be supplemented by consultants or other State agencies with expertise in geology, hydrology, water quality, radiobiology, and engineering disciplines.

To perform the functions involved in evaluation and inspection, it is desirable that there be personnel educated and trained in the physical and/or life sciences, including biology, chemistry, physics and engineering, and that the personnel have had training and experience in radiation protection. For example, the person who will be responsible for the actual performance of evaluation and inspection of all of the various uses of byproduct, source and special nuclear material which might come to the regulatory body should have substantial training and extensive experience in the field of radiation protection. It is desirable that such person have a bachelor's degree or equivalent in the physical or life sciences, and specific training in radiation protection.

It is recognized that there will also be persons performing a more limited function in evaluation and inspection. These persons will perform the day-to-day work of the regulatory program and deal with both routine situations as well as some which will be out of the ordinary. These persons should have a bachelor's degree or equivalent in the physical or life sciences, training in health physics, and approximately two years of actual work experience in the field of radiation protection.

The foregoing are considered desirable qualifications for the staff who will be responsible for the actual performance of evaluation and inspection. In addition, there will probably be trainees associated with the regulatory program who will have an academic background in the physical or life sciences as well as varying amounts of specific training in radiation protection but little or no actual work experience in this field. The background and specific training of these persons will indicate to some extent their potential role in the regulatory program. These trainees, of course, could be used initially to evaluate and inspect those applications of radioactive materials which are considered routine or more standardized from the radiation safety standpoint, for example, inspection of industrial gauges, small research programs, and diagnostic medical programs. As they gain experience and competence in the field, trainees could be used progressively to deal with the more complex or difficult types of radioactive material applications. It is desirable that such trainees have a bachelor's degree or equivalent in the physical or life sciences and specific training in radiation protection. In determining the requirement for academic training of individuals in all of the foregoing categories proper consideration should be given to equivalent competency which has been gained by appropriate technical and radiation protection experience.

It is recognized that radioactive materials and their uses are so varied that the evaluation and inspection functions will requires skills and experience in the different disciplines which will not always reside in one person. The regulatory authority should have the composite of such skills either in its employ or as its command, not only for routine functions, but also for emergency cases.

(a) Number of Personnel.

There are approximately 110 NRC specific licenses in the State of Maine. Under the proposed agreement, the State would assume responsibility for about 105 of these licenses. The Division of Health Engineering is currently staffed with 8 professional persons

Donald Hoxie—Director, Division of Health Engineering. Responsible for the overall supervision of four State-wide regulatory programs, including the Radiological Health Program.

Wallace Hinckley—Assistant Director of Health Engineering. Responsible as Assistant Director for the overall supervision of four Statewide regulatory programs, including the Radiation Control Program.

Wellington Clough Toppan, Jr.—Manager, Radiation Control Program. Responsible for overall supervision of the Radiation Control Program, which regulates x-ray equipment and radionuclide users and conducts environmental monitoring of nuclear power facilities.

Rober Schell—Nuclear Engineering Specialist, Radiation Control Program. Responsible for environmental surveillance of and emergency planning for Maine Yankee Atomic Power Company.

David Breau—Sanitary Engineer II, Drinking Water Program. Responsible for review and approval of engineering plans for water treatment facilities. Backup staff available to the Radiation Control Program.

Linda A. Plausquellic—Radiation Specialist, Radiation Control Program. Performs compliance inspections and registration for x-ray machines. Assists in radioactive materials licensing program.

Jay Carl Hyland—Health Physicist, Radiological Health Program. Responsible for radioactive materials licensing and inspection program.

Cheryl Baker—Chemist II. Responsible for implementation of all radiological testing.

(b) Training.

The academic and specialized short course training for those persons involved in the administration, licensing and inspection of radiation control program is shown below:

Donald C. Hoxie—B.S. Chemical Engineering, University of Maine, M.S. Radiological Health, Rutgers University.

U.S. Public Health Service, Basic Radiological Health. Two week course in 1960.

Oak Ridge Associated Universities, Health Physics Course. A 10-week course ending May 1961.

Brookhaven National Laboratory, Health Physics Training. A 4-week course ending September 1966.

Conference of Radiation Control Program Directors, Training for Radiation Therapy Inspections. November 3–25, 1984.

Conference of Radiation Control Program Directors, Training for Radon Control. November 28–29, 1986.

Wallace W. Hinckley—B.S., Civil Engineering, University of Maine.

University of Oklahoma, NIOSH Course. Safety and Health. January 8 to March 30, 1973.

Federal and Emergency Management Agency. Radiological Emergency Response Planning. 1974 and 1978.

Federal Emergency Management Agency. Basic Radiological Defense Officers Course. Course I, March 7, 1975. Course II, March 14, 1975.

Harvard University, Basic Radiation Protection. April 4–8, 1977.

Harvard University, Environmental Surveillance. May 16–20, 1977.

Harvard University, Planning for Nuclear Emergencies. June 13–17, 1977.

U.S. Nuclear Regulatory Commission, Oak Ridge Associated Universities, Health Physics and Radiation Protection. A 5-week course ending April 14, 1978.

Federal Emergency Management Agency, Radiological Emergency Response Course. August 19–29, 1980.

Federal Emergency Management Agency, Radiological Accident Assessment Course. February 2–6, 1981.

Wellington Clough Toppan, Jr.—B.S., Civil Engineering, Norwich University, M.S., Environmental Engineering, Clarkson College of Technology, M.P.A., Public Administration, University of Maine at Orono.

Federal Emergency Management Agency, Radiological Emergency Response Planning. May 18–22, 1981.

Federal Emergency Management Agency, Basic Radiological Defense Officers. September 8–11, 1981.

Federal Emergency Management Agency, Radiological Accident Assessment. August 23–27, 1982.

New England Radiological Health Committee, Radiological Laboratory Workshop I. April 24–25, 1984.

Federal Emergency Management Agency, Radiological Emergency Response. September 12–21, 1984.

Conference of Radiation Control Program Directors, Training for Radiation Therapy Inspections. October 23–25, 1984.

U.S. Nuclear Regulatory Commission, Health Physics and Radiation Protection. February 3 to March 8, 1985.

New England Radiological Health Committee, Radiological Laboratory Workshop II. April 30 to May 2, 1985.

U.S. Nuclear Regulatory Commission, Introduction to Licensing Practices and Procedures. September 23–27, 1985.

Conference of Radiation Control Program Directors, Health Issues of Non Ionizing Radiation. October 29–30, 1985.

U.S. Environmental Protection, Indoor Radon Workshop. January 21–23, 1986.

U.S. Nuclear Regulatory Commission, Medical Uses of Radionuclides. March 15–20, 1987.

U.S. Nuclear Regulatory Commission, Pressurized Water Reactor Technology. April 28 to May 1, 1987.

U.S. Nuclear Regulatory Commission, Nuclear Transportation Course. August 17–21, 1987.

Southern Maine Vocational Technical School, Radon Mitigation Course. April 12–14, 1988.

Robert J. Schell—B.S., Bioengineering, University of Illinois.

United States Air Force Course, Bioenvironmental Engineering. March 18 to June 21, 1985.

Federal Emergency Management Agency, Radiological Emergency Response. October 16–26, 1985.

U.S. Nuclear Regulatory Commission, Introduction to Health Physics. February 10 to March 14, 1986.

Federal Emergency Management Agency, Radiological Response Planning. June 2–6, 1986.

Federal Emergency Management Agency, Radiologic Accident Assessment. July 14–18, 1986.

University of Massachusetts Medical Center, Medical X-Ray Inspection, August 19–22, 1986.

U.S. Nuclear Regulatory Commission, Medical Uses of Radionuclides. September 8–12, 1986.

U.S. Nuclear Regulatory Commission, PWR Technology. February 23–27, 1987.

U.S. Nuclear Regulatory Commission, CE Technology. June 1–12, 1987.

U.S. Nuclear Regulatory Commission, Inspection Procedures. June 6–10, 1988.

U.S. Nuclear Regulatory Commission, Safety Aspects of Industrial Radiography. August 1–5, 1991.

Federal Emergency Management Agency, Advanced Radiological Accident Assessment. January 23–27, 1989.

David P. Breau—B.S., Civil Engineering, University of Maine at Orono.

Federal Emergency Management Agency, Basic Radiological Defense Officers Course. September 8–11, 1981.

Federal Emergency Management Agency, Nuclear Power Plant Offsite Accident Assessment Course. May 13–17, 1985.

U.S. Nuclear Regulatory Commission, Reactor Theory Operations and Emergency Planning. June 18–21, 1985.

Federal Emergency Management Agency, X-Ray Training. October 16–17, 1985.

Conference of Radiation Control Program Directors, Health Issues of Non Ionizing Radiation. October 29–30, 1985.

Federal Emergency Management Agency, Radiological Emergency Response Course. August 20–29, 1986.

U.S. Nuclear Regulatory Commission, Medical Use of Radionuclides. September 8–12, 1986.

U.S. Nuclear Regulatory Commission, Inspection Procedures Course. September 15–19, 1986.

U.S. Nuclear Regulatory Commission, Health Physics and Radiation Protection. July 20 to August 21, 1987.

U.S. Nuclear Regulatory Commission, Licensing and Practices and Procedures. September 21–25, 1987.

Linda A. Plusquellic—Maine Central Institute, The John Hopkins Hospital School of Radiologic Technology, University of Maine, working toward B.S., Public Administration.

New England Radiological Health Committee, Radon's Impact on State Radiation Control Programs. October 28–29, 1986.

U.S. Department of Health and Human Resources, Medical X-Ray Protection, March 23–27, 1987.

U.S. Department of Health and Human Resources, Basic Course for Investigators: Diagnostic X-Ray. April 27 to May 7, 1987.

Federal Emergency Management Agency, Radiological Emergency Response Course. September 9–18, 1987.
U.S. Nuclear Regulatory Commission, Inspection Procedures Course. September 25–29, 1989.
U.S. Nuclear Regulatory Commission, Medical Uses of Radionuclides. March 18–22, 1991.
Jay Carl Hyland—B.S., Engineering Physics, University of Maine, Orono.
Maine Emergency Management Agency, Fundamentals Course for Radiological Monitors. November 30 to December 1, 1988.
U.S. Nuclear Regulatory Commission, Medical Uses of Radionuclides. March 27–31, 1989.
Federal Emergency Management Agency, Radiological Accident Assessment. May 22–26, 1989.
U.S. Nuclear Regulatory Commission, Inspection Procedures Course. June 19–23, 1989.
U S. Nuclear Regulatory Commission, Health Physics and Radiation Protection. July 10 to August 11, 1989.
U.S. Nuclear Regulatory Commission, Nuclear Transportation. August 14–18, 1989.
Federal Emergency Management Agency, Radiological Emergency Response Course. August 23 to September 1, 1989.
U.S. Nuclear Regulatory Commission, Special Topics Workshop. November 27 to December 1, 1989.
U.S. Nuclear Regulatory Commission, Licensing Practices and Procedures. June 11–15, 1990.
U.S. Nuclear Regulatory Commission, Special Topics Workshop. August 27–29, 1990.
U.S. Nuclear Regulatory Commission, Safety Aspects of Industrial Radiography. September 24–28, 1990.
Cheryl Baker—B.S., Chemistry University of Maine, Orono. U.S. Nuclear Regulatory Commission, Radiochemistry. February 9–13, 1981.
Public Health Laboratory, Radiation Safety in the Laboratory. July 28, 1983.
Federal Emergency Management Agency, Radiological Accident Assessment. March 5–9, 1984.
New England Radiological Health Committee, Radiological Laboratory Workshop. April 24–25, 1984.
Oak Ridge Associated Universities, Health Physics and Radiation Protection. July 9 to August 10, 1984.
New England Radiological Health Committee, Radiation Therapy Inspections. October 23–25, 1984.
New England Radiological Health Committee, Radiological Laboratory Workshop. April 30 to May 2, 1985.
New England Radiological Health Committee, Non Ionizing Radiation. October 29–30, 1985.
New England Radiological Health Committee, Radon's Impact on State Programs. October 28–29, 1986.
New England Radiological Health Committee, Radiological Laboratory Workship. May 5–7, 1987.

Reference: Maine Program Statement.

21. *Conditions Applicable to Special Nuclear Material, Source Material and Tritium.* Nothing in the State's regulatory program shall interfere with the duties imposed on the holder of the materials by the NRC, for example, the duty to report to the NRC, on NRC prescribed forms (1) transfers of special nuclear material, source material and tritium and (2) periodic inventory data.

The State's regulations do not prohibit or interfere with the duties imposed by the NRC on holders of special nuclear material owned by the U.S. Department of Energy or licensed by NRC, such as the responsibility of licensees to supply to the NRC reports of transfer and inventory.

Reference: State of Maine Rules Relating to Radiation Protection Section A.1.

22. *Special Nuclear Material Defined.* Special nuclear material, in quantities not sufficient to form a critical mass, for present purposes means uranium enriched in the isotope U-235 in quantities not exceeding 350 grams of contained U-235; uranium 233 in quantities not exceeding 200 grams: Plutonium in quantities not exceeding 200 grams; or any combination of them in accordance with the following formula: For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all of the kinds of special nuclear material in combination should not exceed "1" (i.e., unity). For example, the following quantities in combination would not exceed the limitation and are within the formula, as follows:

175 (grams contained U–235)/350
50 (grams U–233)/200
50 (grams Pu) = 1/200

(This definition is subject to change by future Commission rule or regulation.)

The definition of special nuclear material in quantities not sufficient to form a critical mass, as contained in the Maine regulations, is uniform with the definition in 10 CFR Part 150.

Reference: State of Maine Rules Relating to Radiation Protection Section A.2.A(62), Definition of Special Nuclear Material in Quantities Not Sufficient to Form a Critical Mass.

Administration

23. *Fair and Impartial Administration.* State practices for assuring the fair and impartial administration of regulatory law, including provision for public participation where appropriate, should be incorporated in procedures for:

(a) Formulation of rules of general applicability;

(b) Approving or denying applications for licenses or authorization to possess and use radioactive materials, and

(c) Taking disciplinary actions against licensees.

The Maine statute and regulations provide for administrative and judicial review of actions taken by the Division of Health Engineering which includes the Maine Radiation Control Program.

Reference: Maine Administrative Procedure Act, State of Maine Rules Relating to Radiation Protection Sections A.9, A.11, C.22, and J.

24. *State Agency Designation.* The State should indicate which agency or agencies will have authority for carrying on the program and should provide the NRC with a summary of that legal authority. There should be assurances against duplicate regulation and licensing by State and local authorities, and it may be desirable that there be a single or central regulatory authority.

The Maine Department of Human Services in which the Maine Radiation Control Program is located has been designated as the State's radiation control agency.

References: Maine Radiation Protection Act, Section 674.1 and 686.

25. *Existing NRC Licenses and Pending Applications.* In effecting the discontinuance of jurisdiction, appropriate arrangements will be made by NRC and the State to ensure that there will be no interference with or interruption of licensed activities or the processing of license applications, by reason of the transfer. For example, one approach might be that the State, in assuming jurisdiction, could recognize and continue in effect, for an appropriate period of time under State law, existing NRC licenses, including licenses for which timely applications for renewal have been filed, except where good cause warrants the earlier reexamination or termination of the license.

Maine regulations have provisions for NRC licensees to possess a like license issued under the Maine regulations and the Maine Act. These licenses will expire either 90 days after receipt from the Agency of a notice of expiration of such license or on the date of expiration specified in the NRC license, whichever is earlier.

Reference: State of Maine Rules Relating to Radiation Protection Section C.19.

26. Relations With Federal Government and Other States. There should be an interchange of Federal and State information and assistance in connection with the issuance of regulations and licenses or authorizations, inspection of licensees, reporting of incidents and violations, and training and education problems.

The proposed agreement declares that the State will use its best efforts to cooperate with the NRC and the other Agreement States in the formulation of standards and regulatory programs for the protection against the hazards of radiation and to assure that the State's program will continue to be compatible with the Commission's program for the regulation of like materials.

Reference: Proposed Agreement between the State of Maine and the Nuclear Regulatory Commission. Article VI.

27. Coverage, Amendments, Reciprocity. The proposed Maine agreement provides for the assumption of regulatory authority over the following categories of materials within the State:

(a) Byproduct material, as defined by Section 11e.(1) of the Atomic Energy Act, as amended.

(b) Source materials.

(c) Special nuclear materials in quantities not sufficient to form a critical mass.

Reference: Proposed Agreement, Article I.

Provision has been made by Maine for the reciprocal recognition of licenses to permit activities within Maine of persons licensed by other jurisdictions. This reciprocity is like that granted under 10 CFR part 150.

Reference: State of Maine Rules Relating to Radiation Protection Section 3.X.

28. NRC and Department of Energy Contractors. The State's regulations provide that certain NRC and DOE contractors or subcontractors are exempt from the State's requirements for licensing and registration of sources of radiation which such persons receive, possess, use, transfer, or acquire.

Reference: State of Maine Rules Relating to Radiation Protection Section A.3.B.

III. Staff Conclusion

Section 274d of the Atomic Energy Act of 1954, as amended, states:

The Commission shall enter into an agreement under subsection b of this section with any State if:

(1) The Governor of the State certifies that the State has a program for the control of radiation hazards adequate to protect the public health and safety with respect to the materials within the State covered by the proposed agreement, and that the State desires to assume regulatory responsibility for such materials; and

(2) The Commission finds that the State program is in accordance with the requirements of subsection o. and in all other respects compatible with the Commission's program for the regulation of such materials, and that the State program is adequate to protect the public health and safety with respect to the materials covered by the proposed amendment.

The staff has concluded that the State of Maine meets the requirements of section 274 of the Act. The State's statutes, regulations, personnel, licensing, inspection and administrative procedures are compatible with those of the Commission and adequate to protect the public health and safety with respect to the materials covered by the proposed agreement. Since the State is not seeking authority over uranium milling activities, subsection o. is not applicable to the proposed Maine agreement

Dated at Rockville, Maryland, this 22nd day of November 1991

For the U.S. Nuclear Regulatory Commission.

Carlton Kammerer,

Director, Office of State Programs.

Appendix A—Agreement Between the United States Nuclear Regulatory Commission and the State of Maine for Discontinuance of Certain Commission Regulatory Authority and Responsibility Within the State Pursuant to Section 274 of the Atomic Energy Act of 1954, as Amended

Whereas, The United States Nuclear Regulatory Commission (hereinafter referred to as the Commission) is authorized under section 274 of the Atomic Energy Act of 1954, as amended (hereinafter referred to as the Act), to enter into agreements with the Governor of any State providing for discontinuance of the regulatory authority of the Commission within the State under Chapters 6, 7, and 8, and section 161 of the Act with respect to byproduct materials as defined in sections 11e.(1) and (2) of the Act, source materials, and special nuclear materials in quantities not sufficient to form a critical mass; and,

Whereas, The Governor of the State of Maine is authorized under Maine Revised Statutes Annotated section 284 to enter into this Agreement with the Commission; and,

Whereas, The Governor of the State of Maine certified on March 5, 1990, that the State of Maine (hereinafter referred to as the State) has a program for the control of radiation hazards adequate to protect the public health and safety with respect to the materials within the State covered by this Agreement, and that the State desires to assume regulatory responsibility for such materials; and,

Whereas, The State and the Commission recognize the desirability and importance of cooperation between the Commission and the State in the formulation of standards for protection against hazards of radiation and in assuring that State and Commission programs for protection against hazards of radiation will be coordinated and compatible; and,

Whereas, The Commission and the State recognize the desirability of reciprocal recognition of licenses and exemptions from licensing of those materials subject to this Agreement; and

Whereas, This Agreement is entered into pursuant to the provisions of the Act, as amended;

Now Therefore, it is hereby agreed between the Commission and the Governor of the State, acting in behalf of the State, as follows:

Article I

Subject to the exceptions provided in Articles II, IV, and V, the Commission shall discontinue, as of the effective date of this Agreement, the regulatory authority of the Commission in the State under chapters 6, 7, and 8, and section 161 of the Act with respect to the following materials:

A. Byproduct materials as defined in section 11e.(1) of the Act;

B. Source materials; and

C. Special nuclear materials in quantities not sufficient to form a critical mass.

Article II

This Agreement does not provide for discontinuance of any authority and the Commission shall retain authority and responsibility with respect to regulation of:

A. The construction and operation of any production or utilization facility;

B. The export from or import into the United States of byproduct, source, or special nuclear material, or of any production or utilization facility;

C. The disposal into the ocean or sea of byproduct, source, or special nuclear waste materials as defined in regulations or orders of the Commission;

D. The disposal of such other byproduct, source, or special nuclear material as the Commission from time to time determines by regulation or order should, because of the hazards or

potential hazards thereof, not be so disposed of without a license from the Commission;

E. The land disposal of source, byproduct and special nuclear material received from other persons; and,

F. The extraction or concentration of source material from source material ore and the management and disposal of the resulting byproduct material.

Article III

This Agreement may be amended, upon application by the State and approval by the Commission, to include the additional area(s) specified in Article II, paragraph E or F, whereby the State can exert regulatory control over the materials stated herein.

Article IV

Notwithstanding this Agreement, the Commission may from time to time by rule, regulation, or order, require that the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source, byproduct, or special nuclear material shall not transfer possession or control of such product except pursuant to a license or an exemption from licensing issued by the Commission.

Article V

This Agreement shall not affect the authority of the Commission under subsection 161 b. or i. of the Act to issue rules, regulations, or orders to protect the common defense and security, to protect restricted data or to guard against the loss or diversion of special nuclear material.

Article VI

The Commission will use its best efforts to cooperate with the State and other Agreement States in the formulation of standards and regulatory programs of the State and the Commission for protection against hazards of radiation and to assure that State and Commission programs for protection against hazards of radiation will be coordinated and compatible. The State will use its best efforts to cooperate with the Commission and other Agreement States in the formulation of standards and regulatory programs of the State and the Commission for protection against hazards of radiation and to assure that the State's program will continue to be compatible with the program of the Commission for the regulation of like materials. The State and the Commission will use their best efforts to keep each other informed of proposed changes in their respective rules and regulations and licensing, inspection and enforcement policies and criteria, and to obtain the comments and assistance of the other party thereon.

Article VII

The Commission and the State agree that it is desirable to provide reciprocal recognition of licenses for the materials listed in Article I licensed by the other party or by any Agreement State. Accordingly, the Commission and the State agree to use their best efforts to develop appropriate rules, regulations, and procedures by which such reciprocity will be accorded.

Article VIII

The Commission, upon its own initiative after reasonable notice and opportunity for hearing to the State, or upon request of the Governor of the State, may terminate or suspend all or part of this Agreement and reassert the licensing and regulatory authority vested in it under the Act if the Commission finds that (1) such termination or suspension is required to protect the public health and safety, or (2) the State has not complied with one or more of the requirements of section 274 of the Act. The Commission may also, pursuant to section 274j of the Act, temporarily suspend all or part of this Agreement if, in the judgement of the Commission, an emergency situation exists requiring immediate action to protect public health and safety and the State has failed to take necessary steps. The Commission shall periodically review this Agreement and actions taken by the State under this Agreement to ensure compliance with section 274 of the Act.

Article IX

This Agreement shall become effective on _____, and shall remain in effect unless and until such time as it is terminated pursuant to Article VIII.

Done at Augusta, Maine, in triplicate, this _____, 1991.

For the U.S. Nuclear Regulatory Commission.

Ivan Selin,

Chairman.

For the State of Maine.

John R. McKernan, Jr.,

Governor.

[FR Doc. 91-30696 Filed 12-23-91; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 030-20541, License No. 52-21350-01, EA 91-171]

Alonso and Carus Iron Works, Inc., Cantano, PR; Order Modifying License (Effective Immediately)

I

Alonso and Carus Iron Works, Inc. (ACIW or Licensee), is the holder of Byproduct Material License No. 52-21350-01 issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR part 34. The license authorizes the Licensee to receive, possess, and utilize sealed sources of iridium-192, not to exceed 100 curies per source, in industrial radiographic exposure devices. The license was issued on August 18, 1983, was renewed on November 15, 1988, and is due to expire on November 30, 1993.

II

Under 10 CFR 34.43(b), during radiographic operations, personnel are required to perform a survey after each exposure to determine that the sealed source is returned to the fully shielded position. In addition, 10 CFR 34.42, in conjunction with 10 CFR 20.203(c), requires, in part, that personnel conspicuously post each high radiation area with a sign or signs bearing the radiation caution symbol and the words "Caution High Radiation Area."

Jose A. Ruiz-Carlo is a radiographer and is named on the license as the Assistant Radiation Safety Officer. During an NRC inspection on October 10, 1091, an NRC inspector counseled Mr. Ruiz regarding the importance of performing radiation surveys of the radiographic exposure device, in accordance with 10 CFR 34.43(b), after each exposure to determine that the sealed source has been returned to its shielded position. Additionally, the NRC inspector advised Mr. Ruiz to use proper radiation survey technique and exercise more precise survey methods when approaching the radiographic exposure device after each exposure. Mr. Ruiz assured the inspector that he would use better technique and methods when performing such surveys in future radiographic operations.

On October 11, 1991, the NRC inspector observed Mr. Ruiz conducting radiographic operations at San Juan Airport, San Juan, Puerto Rico. Contrary to the above referenced NRC requirements:

(1) Mr. Ruiz conducted radiographic operations on at least three occasions without performing surveys of the radiographic exposure device to determine that the sealed source had

been returned to its fully shielded position after each source exposure. A portable survey meter was located approximately 10 feet from the exposure device, but Mr. Ruiz failed to use the survey meter after each exposure; and

(2) Mr. Ruiz failed to post signs for the high radiation area when the radiographic source was exposed.

On October 18, 1991, the NRC inspector contacted Mr. Ruiz by telephone and discussed what he had observed on October 11, 1991. Additionally, the inspector discussed with Mr. Ruiz the October 10, 1991, conversation regarding the importance of radiation surveys and the use of proper technique when approaching radiographic exposure devices. Mr. Ruiz did not deny the failure to perform required surveys on October 11, 1991, and admitted to the inspector that he performed an initial survey after the first radiographic exposure but failed to conduct any subsequent surveys. Mr. Ruiz offered no further explanation for his actions.

(I)

Mr. Ruiz is experienced, trained, and knowledgeable concerning NRC requirements pertaining to surveys and to securing the sealed source in the fully shielded position after each exposure. Mr. Ruiz has been an authorized user of licensed material for over seven years. Additionally, Mr. Ruiz has served as an Assistant Radiation Safety Officer at ACIW for over three years and, therefore, is responsible in part for assuring that the Licensee meets NRC requirements. The NRC inspector directly observed Mr. Ruiz violating survey requirements within 24 hours of an earlier specific conversation between the inspector and Mr. Ruiz regarding the required surveys. Mr. Ruiz subsequently admitted to the inspector that he failed to perform the required surveys.

The performance of licensed activities requires meticulous attention to detail by responsible personnel to ensure that licensed activities are conducted safely and in accordance with Commission requirements. This attention to detail is particularly important during the performance of industrial radiography, given the activity levels of the radioactive sources. The failure to properly control the use of radiography devices through the performance of necessary radiation surveys and posting of high radiation areas could result in significant exposures to the public, including the Licensee's employees. Willful violation of requirements designed to protect the public health and safety cannot be tolerated.

While the NRC investigation of this matter is continuing, it appears, based on the above, that Mr. Ruiz willfully failed to meet inportant safety requirements designed to protect the public health and safety, including that of the Licensee's employees. As a result of this willful violation to perform surveys and the failure to comply with posting requirements, the NRC does not have reasonable assurance that Mr. Ruiz will comply with regulatory requirements.

Consequently, I lack the requisite reasonable assurance that, with Mr. Ruiz as a radiographer, a supervisor of radiographers, the Radiation Safety Officer, or an Assistant Radiation Safety Officer, the Licensee's current operations under License No. 52–21350–01 can be conducted in compliance with the Commission's requirements and that the health and safety of the public, including the Licensee's employees, will be protected. Therefore, I have determined that License No. 52–21350–01 should be modified to prohibit the utilization of Mr. Jose A. Ruiz-Carlo in certain licensed activities. Furthermore, pursuant to 10 CFR 2.202 (56 FR 40664 (August 15, 1991)), I have concluded that the public health, safety, and interest require that this Order be immediately effective pending further NRC action based upon the evaluation of the results of the NRC investigation.

IV

According, pursuant to section 81, 161b, 161i, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202 and 10 CFR part 34, *It Is Hereby Ordered, Effective Immediately, That License No. 52–21350–01 Is Modified To Include the Following Conditions:*

Alonso and Carus Iron Works, Inc., shall not utilize Mr. Jose A. Ruiz-Carlo as a radiographer, a supervisor of radiographers, or as a Radiation Safety Officer, including an Assistant Radiation Safety Officer, until further NRC action based upon the results of its investigation of this matter.

The Regional Administrator, Region II, may, in writing, relax or rescind any of the above conditions upon demonstration by the Licensee of good cause.

V

In accordance with 10 CFR 2.202, the Licensee must, and Mr. Jose A. Ruiz-Carlo or any other person adversely affected by this Order may, submit an answer to this Order under oath or affirmation within 20 days of the date of this Order. Within the same time period, such persons may request a hearing, which may be included in the answer. The answer may consent to the Order. Unless the answer consents to the Order, the answer shall specifically admit or deny each allegation or charge made in the Order, set forth the matters of fact and law on which the Licensee, Mr. Jose A. Ruiz-Carlo, or other person adversely affected relies, and the reasons are to why the Order should not have been issued. Any answer or request for a hearing shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission, Attn: Chief, Docketing and Service Section, Washington, DC 2055. Copies also shall be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, to the Assistant General Counsel for Hearings and Enforcement at the same address, to the Regional Administrator, NRC Region II at 101 Marietta Street, NW., suite 2900, Atlanta, Georgia 30323, and to the Licensee if the answer or hearing request is by a person other than the Licensee. If a person other than the Licensee or Mr. Ruiz requests a hearing, that person shall set forth with particularity the manner in which his or her interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.714(d).

If a hearing is requested by the Licensee, Mr. Jose A. Ruiz-Carlo, or a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearing. If a hearing is held, the issue to be considered at such hearing shall be whether this Order should be sustained.

VI

In the absence of any request for hearing, this Order shall be final 20 days from the date of this Order without further order or proceedings.

An Answer or a Request for Hearing Shall not Stay the Immediate Effectiveness of this Order.

Dated at Rockville, Maryland this 13th day of December 1991.

For the Nuclear Regulatory Commission.

James Lieberman,

Director, Office of Enforcement.

[FR Doc. 91–30694 Filed 12–23–91; 8:45 am]

BILLING CODE 7590–01–M

[Docket Nos. 50–220 and 50–410]

Niagara Mohawk Power Corp.; Nine Mile Point Nuclear Station, Unit Nos. 1 and 2; Exemption

I

Niagara Mohawk Power Corporation (NMPC or the licensee) is the holder of

Facility Operating Licenses Nos. DPR–63 and NPF–54, which authorize operation of Nine Mile Point Nuclear Station (the facility), at steady-state reactor power levels not in excess of 1850 megawatts thermal for Unit No. 1 and 3323 megawatts thermal for Unit No. 2. The licenses provide, among other things, that they are subject to all rules, regulations and Orders of the Nuclear Regulatory Commission (the Commission or NRC) now or hereafter in effect. The facilities consist of two boiling water reactors located at the licensee's site in Oswego County, New York.

II

Section 50.54(q) of 10 CFR part 50 requires a licensee authorized to operate a nuclear power reactor to follow and maintain in effect emergency plans which meet the standards of 10 CFR 50.47(b) and the requirements of Appendix E to 10 CFR part 50. Section IV.F.2 of appendix E requires that each licensee at each site shall annually exercise its emergency plan.

The NRC may grant exemptions from the requirements of the regulations which, pursuant to 10 CFR 50.12(a), are (1) authorized by law, will not present an undue risk to the public health and safety, and are consistent with the common defense and security; and (2) present special circumstances. Section 50.12(a)(2)(ii) of 10 CFR Part 50 describes the special circumstances for an exemption where the application of the regulation in the particular circumstances would not serve the underlying purpose of the rule or is not necessary to achieve the underlying purpose of the rule. The underlying purpose of appendix E, Section IV.F.2, is to demonstrate that the emergency plan is adequate and capable of being implemented, and that the state of emergency preparedness provides reasonable assurance that adequate protective measures can be taken in the event of a radiological emergency.

III

By letter dated September 19, 1991, the licensee requested an exemption from the requirement of 10 CFR part 50, appendix E, section IV.F.2, to conduct an annual exercise of the Nine Mile Point Emergency Plan in 1991. The licensee also submitted additional information by letter dated November 14, 1991, in response to the NRC staff's request for additional information dated October 23, 1991. The licensee had planned to conduct an exercise of its emergency plan on October 1, 1991, with the partial participation of State and local emergency response organizations. The scheduled exercise was an annual licensee off-year exercise and the Federal Emergency Management Agency (FEMA) was not scheduled to observe the exercise. The previous emergency preparedness exercise at the Nine Mile Point Nuclear Station, conducted on October 2, 1990, was also a partial participation exercise. A full participation exercise with the State of New York and Oswego County was conducted on August 7, 1991, at the James A. Fitzpatrick Nuclear Power Plant, which is immediately adjacent to the Nine Mile Point Nuclear Station. The licensee requested that an exemption be granted because the requirement to perform an exercise of the Nine Mile Point Emergency Plan in 1991 was not necessary to achieve the underlying purpose of the emergency planning rule in that the emergency plan was adequately exercised and demonstrated in 1991 in the licensee's response to the Unit 2 loss of annunciators event that occurred on August 13, 1991. The schedule for future exercises will not be affected by this one-time exemption.

To support its request, the licensee provided the following information to the NRC as an attachment to the September 19, 1991, exemption request:

Niagara Mohawk's response to the Site Area Emergency exercised the major portions of the Nine Mile Point Nuclear Station's emergency response capabilities in the manner described by the 10 CFR 50.47(b)14 requirement for periodic exercises. The Site Area Emergency tested the adequacy of timing and content of implementing procedures and methods, emergency equipment and communications networks, and ensured that emergency response organization personnel are familiar with their duties. The following are specific supporting examples:

1. During the Site Area Emergency, all emergency response facilities were activated. The Site Emergency Plan was satisfactorily implemented.

2. A full staff of radiological and dose assessment personnel evaluated effluent monitors and directed survey teams. Actual soil, air and water samples were taken and the dose assessment computer program model was run using the default values of the Unit 2 Updated Safety Analysis Report.

3. Oswego County officials activated the Oswego County Emergency Operations Center and established the necessary traffic control points for site access control. New York State representatives activated the New York State Emergency Operations Center and participated at the County Emergency Operations Center. Niagara Mohawk, Oswego County and New York State representatives briefed the general public, through the news media at the Joint News Center. Also, Niagara Mohawk, New York State, and Oswego County continually conferred on protective actions.

4. The Resident Inspectors, a Region I Radiological Inspector, and two Region I Security Inspectors observed the Site Area Emergency directly. An Augmented Inspection Team (AIT), including a Region I Senior Emergency Preparedness Inspector, immediately investigated the event.

5. Niagara Mohawk held a formal critique, attended by the Augmented Inspection Team's Senior Emergency Preparedness Inspector, to evaluate the emergency response and to identify areas in need of improvement. The critique participants concluded that the emergency response had been satisfactorily implemented in a professional manner.

The only significant area for improvement identified by Niagara Mohawk was personnel accountability. Personnel accountability was not initiated in a timely manner. As a corrective action, Security supervisors have been given specific direction to initiate personnel accountability as soon as station evacuation announcement is made. Otherwise, all the objectives for an emergency exercise listed in our June 28 letter were satisfactorily accomplished during the emergency response.

Niagara Mohawk has consulted with Oswego County and New York State officials concerning an exemption from the October 1, 1991 exercise. Both authorities concurred with our request for exemption.

On August 13, 1991 at approximately 5:48 a.m., Nine Mile Point Unit 2 experienced a loss of control room annunciators, loss of Balance of Plant (BOP) instrumentation, a turbine/generator trip, and an automatic reactor scram. The loss of annunciators and BOP instrumentation resulted from a loss of five (5) non-safety-related uninterruptible power supplies when the phase B main transformer failed. The turbine/generator trip was also caused by failure of the phase B main transformer. The turbine/generator trip provided an automatic reactor scram. At 6 a.m., a Site Area Emergency was declared based upon the emergency action level criteria of S-EAP–2, "Classification of Emergency Conditions," being exceeded.

At 6:22 a.m., power was restored to the annunciators and instrumentation and reactor shutdown was verified. At 7:06 a.m., the plant commenced a normal cooldown using secondary systems and achieved cold shutdown at 6:46 p.m. AT 7:42 p.m., the Site Area Emergency was terminated and a recovery plan was implemented.

A Region I Augmented Inspection Team (AIT) was dispatched to the site to verify the circumstances and evaluate the significance of the event. Among the charter of AIT activities was the task of evaluating operator response and reviewing the adequacy of both the Niagara Mohawk and Power Authority of the State of New York (FitzPatrick) emergency response. The licensee's Site Emergency Plan was effectively implemented to protect public health and safety. One non-cited violation was identified regarding notification of onsite emergency response organization personnel. Other concerns were also identified with regards to the site access of incoming personnel and accountability of personnel within the protected area. The

licensee is taking appropriate corrective actions to resolve these items. Due to the potential safety significance and regulatory questions raised by the event, the AIT was upgraded to an NRC Incident Investigation Team on August 15, 1991. However, the emergency preparedness aspects of the event were assigned to Region I. The findings of Region I regarding emergency preparedness are documented in Inspection Reports 50–220/91–19 and 50–410/91–19, dated November 5, 1991.

In response to the August 13, 1991, event, the following key elements of the Nine Mile Point emergency plan were demonstrated:

- Classification of the event in accordance with the emergency plan implementing procedures.
- Notification of State, local and Federal emergency response organizations and personnel.
- Activation, staffing and operation of the emergency response facilities including the Control Room, Technical Support Center, Operational Support Center, Emergency Operations Facility, NMPC Corporate Emergency Operations Center, Joint News Center, Oswego County Emergency Operations Center, and the New York State Emergency Operations Center.
- Communications between emergency facilities, principal response organizations and emergency personnel.
- Accident assessment involving the methods, systems and equipment necessary for assessing and monitoring the actual consequences of the event, including both an engineering assessment of plant status and an assessment of radiological consequences.
- Media and public information dissemination through the issuance of press releases and the conduct of press briefings at the Joint News Center.
- Recovery planning, including the formation of a recovery organization, identification of resource and the development of recovery actions.

Licensee response activities included the development of initial and followup messages to offsite organizations; continuous communication with the NRC; station accountability; security access control; dispatch of inplant, onsite, and offsite monitoring teams; formulation of offsite dose projections, including the determination of meteorological dispersion; collection and analysis of environmental samples; analysis of inplant radioactivity levels; and interfacing with State and local emergency operations personnel. Although protective action recommendations for the public were not required to be issued based on plant parameters and field monitoring information, the necessity for issuing such recommendations was considered by the licensee during the course of the event.

After the August 13, 1991, event, the licensee conducted a critique of the emergency response effort. The licensee developed a list of "opportunities for improvement" resulting from the implementation of the Nine Mile Point Emergency Plan under actual conditions. The licensee has established an action plan to evaluate and address this list of "opportunities for improvement."

In addition to the response to the August 13, 1991, event, other licensee activities related to the demonstration of emergency preparedness in 1991 included a Casualty Control Drill conducted on February 26, 1991, a practice drill conducted on August 1, 1991, quarterly fire drills for each shift of the onsite Fire Department, a Site Emergency Accountability drill conducted on April 30, 1991, an Offsite Fire/Offsite Medical/Off-Hours Notification drill conducted on June 4, 1991, an Environmental Monitoring drill conducted on October 9, 1991, and an Off-Hours Notification/Station Evacuation drill on October 29, 1991. For each of these drills, the licensee conducted an evaluation and initiated corrective actions to address items identified as "opportunities for improvement."

The most recent NRC Systematic Assessment of Licensee Performance (SALP) Report for Nine Mile Point issued on August 2, 1991, for the period March 1, 1990, through March 31, 1991, indicated good overall licensee performance. Specifically, in the functional area of emergency preparedness, licensee performance was rated Category 1, indicating a superior level of performance. Inspection activities conducted since the SALP report indicate no change in level of performance regarding emergency preparedness.

IV

Based on a review of the licensee's request for an exemption from the requirement to conduct an exercise of the Nine Mile Point Emergency Plan in 1991, the NRC staff finds that the underlying purpose of the regulation has been achieved through the licensee's response to the August 13, 1991, event. The licensee fully activated and staffed its emergency response facilities and performed all necessary response actions under actual conditions. Both onsite and offsite emergency response organizations were involved in the event. The response to the August 13, 1991, event tested the adequacy of the emergency plan implementing procedures, tested emergency equipment and communications networks, and provided a unique opportunity to ensure that emergency organization personnel were familiar with their duties. The licensee has identified corrective actions to improve the level of emergency preparedness at the Nine Mile Point Nuclear Station through critiques with emergency personnel following the event. The licensee has established an action plan which NRC Region I will monitor progress on and evaluate in future inspections. The NRC staff concludes that the licensee satisfactorily demonstrated the adequacy of the Nine Mile Point Emergency Plan and its capability of being implemented in the response to the August 13, 1991, event. Thus, a further exercise in 1991 is not necessary to achieve the underlying purpose of the rule. The requested exemption from the requirement of 10 CFR part 50, appendix E, section IV.F, to perform an exercise of the Nine Mile Point Emergency Plan in 1991, will not adversely affect the overall state of emergency preparedness at the Nine Mile Point site because the emergency plan was adequately exercised and demonstrated during the licensee's response to the August 13, 1991, event.

For these reasons, the Commission has determined that, pursuant to 10 CFR 50.12, the exemption requested by the licensee's letter dated September 19, 1991, as discussed above, is authorized by law, will not present an undue risk to the public health and safety, and is consistent with the common defense and security and that special circumstances are present as set forth in 10 CFR 50.12(a)(2)(ii).

Pursuant to 10 CFR 51.32, the Commission has determined that granting of this Exemption will have no significant impact on the environment (October 31, 1991, 56 FR 56105). A copy of the licensee's request for exemption and supporting documentation is available for public inspection at the Commission's Public Document Room, 2120 L Street, Washington, DC 20555 and at the Reference and Documents Department, Penfield Library, State University of New York, Oswego, New York 13126. Copies may be obtained upon written request to the U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Director, Division of Reactor Projects—I/II.

This exemption is effective upon issuance.

Dated at Rockville, Maryland, this 16th day of December 1991.

For the Nuclear Regulatory Commission.

Steven A. Varga,

Director, Division of Reactor Projects—I/II, Office of Nuclear Reactor Regulation.

[FR Doc. 91-30695 Filed 12-23-91; 8:45 am]

BILLING CODE 7590-01-M

PHYSICIAN PAYMENT REVIEW COMMISSION

Commission Meeting

AGENCY: Physician Payment Review Commission.

ACTION: Notice of meeting.

SUMMARY: The Commission will hold its next public meetings on Thursday and Friday, January 16 and 17, 1992 at the Grand Hotel, 2350 M Street NW., Washington, DC, 202-429-0100. Thursday's meeting will be in the Ballroom on the lower conference level and Friday's meeting will be in room V. At these meetings, the Commission will focus on recommendations to be included in its next annual report, due to Congress April 1, 1992.

ADDRESSES: The Commission is located at 2120 L Street NW. in suite 510, Washington, DC. The telephone number is 202/653-7220.

FOR FURTHER INFORMATION CONTACT: Lauren LeRoy, Deputy Director, 202/653-7220.

SUPPLEMENTARY INFORMATION: Information about the exact agenda for the public meetings can be obtained on Friday, January 10, 1992. Copies of the agenda can be mailed at that time. Please direct all requests for the agenda to the Commission's receptionist.

Paul B. Ginsburg,

Executive Director.

[FR Doc. 91-30676 Filed 12-23-91; 8:45 am]

BILLING CODE 6820-SE-M

POSTAL RATE COMMISSION

[Docket No. A92-5]

Notice and Order Accepting Appeal and Establishing Procedural Schedule Under 39 U.S.C. 404(b)(5)

Issued December 18, 1991.

Before Commissioners: George W. Haley, Chairman; Henry R. Folsom, Vice-Chairman; John W. Crutcher; W. H. "Trey" LeBlanc III; H. Edward Quick, Jr.

In the Matter of: Skene, Mississippi 38775 (Matt Dakin III, Petitioner).

Docket Number: A92-5.

Name of Affected Post Office: Skene, Mississippi 38775.

Name(s) of Petitioner(s): Matt Dakin III.

Type of Determination: Closing.

Date of Filing of Appeal Papers: December 17, 1991.

Categories of Issues Apparently Raised:

1. Effect on the community [39 U.S.C. 404(b)(2)(A)];

2. Effect on postal services [39 U.S.C. 404(b)(2)(C)]

Other legal issues may be disclosed by the record when it is filed; or, conversely, the determination made by the Postal Service may be found to dispose of one or more of these issues.

In the interest of expedition, in light of the 120-day decision schedule [39 U.S.C. 404(b)(5)], the Commission reserves the right to request of the Postal Service memoranda of law on any appropriate issue. If requested, such memoranda will be due 20 days from the issuance of the request; a copy shall be served on the petitioner. In a brief or motion to dismiss or affirm, the Postal Service may incorporate by reference any such memoranda previously filed.

The Commission orders:

(A) The record in this appeal shall be filed on or before January 2, 1992.

(B) The Secretary shall publish this Notice and Order and Procedural Schedule in the **Federal Register.**

By the Commission.

Cyril J. Pittack,

Acting Secretary.

Appendix

December 17, 1991—Filing of Petition

December 18, 1991—Notice and Order of Filing of Appeal

January 13, 1992—Last day for filing of petitions to intervene (see 39 CFR 3001.111(b))

January 21, 1992—Petitioner's Participant Statement or Initial Brief (see 39 CFR 3001.115(a)

February 10, 1992—Postal Service Answering Brief (see 39 CFR 3001.115(c))

February 25, 1992—Petitioner's Reply Brief should petitioner choose to file one (see 39 CFR 3001.115(d))

March 3, 1992—Deadline for motions by any party requesting oral argument. The Commission will schedule oral argument only when it is a necessary addition to the written filings (see 39 CFR 3002.116)

April 15, 1992—Expiration of 120-day decisional schedule (see 39 U.S.C. 404(b)(5))

[FR Doc. 91-30655 Filed 12-23-91; 8:45 am]

BILLING CODE 7710-FW-M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-30085; File No. SR-DTC-91-21]

Self-Regulatory Organizations; Depository Trust Company; Order Approving a Proposed Rule Change Relating to the Cancellation of Pending Deliver Orders in the Next-Day Funds Settlement and Same-Day Funds Settlement Systems

December 16, 1991.

On September 26, 1991, The Depository Trust Company ("DTC") filed a proposed rule change (File No. SR-DTC-91-21) with the Securities and Exchange Commission ("Commission") under section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"). The proposed rule change relates to DTC's Pending Transaction Inquiry ("PEND") function. The Commission published notice of this proposed rule change in the **Federal Register** on October 21, 1991. No public comments were received. For the reasons discussed below, the Commission is approving the proposed rule change.

I. Description

The proposal establishes procedures whereby delivering DTC participants, through the PEND function of their Participant Terminal System ("PTS") screen, may cancel pending (recycling) deliver orders in the next-day funds settlement ("NDFS") and same-day funds settlement ("SDFS") systems that they no longer want DTC to process.[1] Under the PEND cancel function, a participant may cancel any non-Continuous Net Settlement (CNS) pending deliver order to which that participant is the deliverer. Neither SDFS payment orders nor deliver orders involving securities undergoing reorganizational activity may be cancelled. The cancel function is designed to allow a participant to cancel erroneous deliver orders. A participant may have directed a deliver order to the wrong participant or may have directed the order to the correct participant but entered the wrong amount or the wrong security. The cancel function eliminates unnecessary movements and the associated risk by allowing a delivering

[1] Currently, the PEND function recycles certain deliver orders when the system is unable to act on a participant's instructions. A deliver order in the NDFS system will pend or recycle if there are insufficient securities in the participant's DTC account to make the delivery. A deliver order in the SDFS system will pend if the participant has a collateral monitor deficiency, a debit cap deficiency or a share deficiency at DTC.

party to cancel such deliver orders unilaterally.

After a participant cancels a pending deliver order, DTC sends the participant a ticket confirming the cancellation and identifying the transaction by quantity, dollar amount and CUSIP numbers. Cancelled transactions are displayed on PEND's inquity screen for the remainder of the day on which they are cancelled.

II. Discussion

The Commission believes that DTC's proposal is consistent with Section 17A of the Act in that it promotes the prompt and accurate clearance and settlement of securities transactions and enhances the safeguarding of funds and securities in DTC's possession or under its control. Accordingly, for the reasons discussed below, the Commission is approving the proposal.

The purpose of the PEND cancel option is to allow participants to cancel erroneous deliver orders and thus prevent the need to redeliver such orders and reduce the risk associated with erroneous deliveries. While some participants may use the PEND cancel option to cancel deliver orders that are not erroneous, this in no way alters underlying obligations between the parties, including the obligation to deliver securities or funds to another party, either through DTC or by some other delivery mechanism.

The Commission believes that DTC has sufficient capacity to handle any potential volume increase associated with the PEND cancel function. DTC has represented that the cancel function will account for approximately 100 activities per day; thus, the function can easily be accommodated within DTC's present projected capacity. Furthermore, DTC has considered the effect of the program on controls in place to prevent unauthorized access to and misuse of its automated system.[2] DTC has concluded that the program raises no new issues of computer security and that its existing controls are adequate.

In the SDFS system, a securities delivery may be blocked if the participant has exceeded its net debit cap [3] or its collateral monitor [4] limit. Under DTC's current rules, to unblock a recycling delivery, a participant may increase its net debit cap or collateral by wiring additional funds or securities to DTC, or by waiting for a delivery to its account that reduces its net debit cap or collateral monitor to a level that allows the delivery to occur. Without a cancellation feature, erroneous blocked deliveries may prevent the execution of other deliveries. Allowing participants to cancel erroneous blocked or pending deliveries will permit other deliver orders to occur without increasing DTC's risk exposure.

In the NDFS and SDFS systems, a deliver order may pend until sufficient securities are in the participant's account to allow the completion of the delivery. In the SDFS system, deliver orders are deleted at the end of the day, but many times these erroneous delivery orders are executed late in the day, often too late for redelivery. Through the PEND cancel function, however, a participant may cancel an erroneous delivery order and avoid the delay and risk involved in seeking the return of erroneous deliver orders. In addition, DTC will report to participants all deliver orders that have been cancelled as a result of the PEND cancel function. Thus, DTC participants will have an audit trail of their cancellations. Therefore, the Commission believes that the PEND cancel function promotes the prompt and accurate clearance and settlement of securities and the safeguarding of funds and securities in DTC's custody or control or for which it is responsible, particularly where a participant enters an erroneous delivery instruction.

III. Conclusion

On the basis of the foregoing, the Commission finds that the proposed rule change is consistent with the Act and, in particular, with section 17A of the Act, and the rules and regulations thereunder.

It is therefore ordered, pursuant to section 19(b)(2) of the Act, That the proposed rule change (File No. SR–DTC–91–21) be, and hereby is, approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 91–30627 Filed 12–23–91; 8:45 am]

BILLING CODE 8010–01–M

[2] See Letter from Jack R. Wiener, Associate Counsel, DTC, to Ester Saverson, Branch Chief, Division of Market Regulation, SEC (September 27, 1991).

[3] A debit cap is the maximum debit a participant may accumulate at one time in the SDFS system. When a participant reaches its debit cap, it may not send additional deliver orders in the SDFS system until its debit is reduced below the cap. See DTC Rule 1 and rule 9(A).

[4] Collateral monitor is the sum of the net debit or net credit in a participant's SDFS settlement account and the collateral value in any account within an Account Family or allocated to an Account Family. See DTC rule 1 and rule 9(A).

Self-Regulatory Organizations; Applications for Unlisted Trading Privileges and of Opportunity for Hearing; Pacific Stock Exchange, Inc.

December 18, 1991.

The above named national securities exchange has filed applications with the Securities and Exchange Commission ("Commission") pursuant to section 12(f)(1)(B) of the Securities Exchange Act of 1934 and rule 12f–1 thereunder for unlisted trading privileges in the following securities:

Owens-Illinois, Inc.
Common Stock, $.01 Par Value (File No. 7–7690)
Nerco, Inc.
Common Stock, No Par Value (File No. 7–7691)
Jundt Growth Fund, Inc.
Common Stock, $.01 Par Value (File No. 7–7692)
The Presley Co.'s
Common Stock, $.01 Par Value (File No. 7–7693)
General Motors Corporation
Depositary Shares (each representing ¼ of a share of Series B Preference Stock, $25.00 Par Value) (File No. 7–7694)

These securities are listed and registered on one or more other national securities exchange and are reported in the consolidated transaction reporting system.

Interested persons are invited to submit on or before January 10, 1992, written data, views and arguments concerning the above-referenced application. Persons desiring to make written comments should file three copies thereof with the Secretary of the Securities and Exchange Commission, 450 5th Street NW., Washington, DC 20549. Following this opportunity for hearing, the Commission will approve the application if it finds, based upon all the information available to it, that the extensions of unlisted trading privileges pursuant to such applications are consistent with the maintenance of fair and orderly markets and the protection of investors.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority

Jonathan G. Katz,

Secretary.

[FR Doc. 91–30685 Field 12–23–91; 8:45 am]

BILLING CODE 8010–01–M

Issuer Delisting; Application To Withdraw From Listing and Registration; Greiner Engineering, Inc., Common Stock, $0.50 Par Value (File No. 1-6082)

December 18, 1991.

Greiner Engineering, Inc. ("Company") has filed an application with the Securities and Exchange Commission ("Commission") pursuant to section 12(d) of the Securities Exchange Act of 1934 and rule 12d2-2(d) promulgated thereunder to withdraw the above specified security from listing and registration on the American Stock Exchange, Inc. ("Amex").

The reason alleged in the application for withdrawing this security from listing and registration include the following:

The Company's Common Stock also currently is listed on the Pacific Stock Exchange ("PSE") and effective at the opening of business on December 20, 1991, the Company's common stock commenced trading on the New York Stock Exchange ("NYSE") as well. In making the decision to withdraw the Common Stock from listing on the Amex, the Company considered the direct and indirect costs and expenses attendant on maintaining the listing of the Common Stock on the NYSE and the PSE, as well as on the Amex. The Company does not see any particular advantage in the continued trading of the Common Stock on the Amex, in addition to its trading on the NYSE and the PSE, and believes that such continued listing would fragment the market for its Common Stock.

Any interested person may, on or before January 10, 1992, submit by letter to the Secretary of the Commission, 450 Fifth Street NW., Washington, DC 20549, facts bearing upon whether the application has been made in accordance with the rules of the Exchanges and what terms, if any, should be imposed by the Commission for the protection of investors. The Commission, based on the information submitted to it, will issue an order granting the application after the date mentioned above, unless the Commission determines to order a hearing on the matter.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 91-30683 Filed 12-23-91; 8:45 am]

BILLING CODE 8010-01-M

Issuer Delisting; Application To Withdraw From Listing and Registration; (US West, Inc., Common Stock, No Par Value) File No. 1-8611

December 18, 1991.

US West, Inc. ("Company") has filed an application with the Securities and Exchange Commission, pursuant to section 12(d) of the Securities Exchange Act of 1934 ("Act") and rule 12d2-2(d) promulgated thereunder, to withdraw the above specified security from listing and registration on the Boston Stock Exchange, Inc. ("BSE"); Midwest Stock Exchange, Inc. ("MSE"); Pacific Stock Exchange, Inc. ("PSE"); and Philadelphia Stock Exchange, Inc. ("Phlx").

The reasons alleged in the application for withdrawing this security from listing and registration include the following:

According to the Company, it intends to retain the listing of the Common Stock from the BSE, MSE, PSE, and Phlx where there is limited trading.

Any interested person may, on or before January 10, 1992 submit by letter to the Secretary of the Securities and Exchange Commission, 450 Fifth Street NW., Washington, DC 20549, facts bearing upon whether the application has been made in accordance with the rules of the exchanges and what terms, if any, should be imposed by the Commission for the protection of investors. The Commission, based on the information submitted to it, will issue an order granting the application after the date mentioned above, unless the Commission determines to order a hearing on the matter.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 91-30684 Filed 12-23-91; 8:45 am]

BILLING CODE 8010-01-M

Sunshine Act Meetings

Federal Register
Vol. 56, No. 247
Tuesday, December 24, 1991

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

COMMODITY FUTURES TRADING COMMISSION

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: 56 F.R. 64001.

PREVIOUSLY ANNOUNCED TIME AND DATE OF MEETING: 10:00 a.m., Friday, January 3, 1992.

CHANGES IN THE MEETING: The Commodity Futures Trading Commission has postponed the open meeting to discuss Rule 4.7—proposed rules on accredited investors to Tuesday, January 14, 1992. Also, added to that meeting are the final rules for Guidelines 1. The meeting will be held at 10:00 a.m. in the Lower Level Hearing Room.

CONTACT PERSON FOR MORE INFORMATION: Jean A. Webb, 254–6314.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 91–30749 Filed 12–19–91; 4:39 pm]

BILLING CODE 6351–01–M

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of Agency Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby give that at 10:03 a.m. on Thursday, December 19, 1991, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session to consider the following:

Matters relating to the probable failure of a certain insured bank.

Recommendations concerning administrative enforcement proceedings.

Recommendation regarding the liquidation of depository institutions' assets acquired by the Corporation in its capacity as receiver, liquidator, or liquidating agent of those assets:

Case No. 47,767
Community National Bank and Trust Company of New York New York City (Oakwood), New York

Application of First Interstate Bank, Ltd., Los Angeles, California, for consent to indirectly acquire through its subsidiary all outstanding stock of First Interstate Portfolio Services Limited, Great Britain.

Application of United Security Bank, National Association, Fresno, California, for consent to convert the Savings Association Insurance Fund insured deposits of the Fresno Branch of University Savings Bank, Newport Beach, California, to Bank Insurance Fund insured deposits upon the acquisition of the Fresno Branch by United Security Bank, National Association.

Matter relating to the Corporation's corporate activities.

Requests for waiver of the cross-guaranty provisions of the Federal Deposit Insurance Act.

Personnel Matters.

In calling the meeting, the Board determined, on motion of Director C. C. Hope, Jr. (Appointive), seconded by Director Robert L. Clarke (Comptroller of the Currency), concurred in by Director T. Timothy Ryan, Jr. (Office of Thrift Supervision), Chairman William Taylor, and Vice Chairman Andrew C. Hove, Jr., that Corporation business required its consideration of the matters on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting by authority of subsections (c)(2), (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), and (c)(9)(B) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(2), (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), and (c)(9)(B)).

The meeting was held in the Board Room of the FDIC Building located at 550—17th Street, NW., Washington, DC.

Dated: December 19, 1991.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Deputy Executive Secretary.

[FR Doc. 91–30748 Filed 12–19–91; 4:38 pm]

BILLING CODE 6714–01–M

NUCLEAR REGULATORY COMMISSION

DATES: Weeks of December 23 and 30, 1991 and January 6 and 13, 1992

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland

STATUS: Open and Closed

MATTERS TO BE CONSIDERED:

Week of December 23

There are no Commission meetings scheduled for the Week of December 23.

Week of December 30—Tentative

There are no Commission meetings scheduled for the Week of December 30.

Week of January 6—Tentative

Friday, January 10

11:30 a.m.
Affirmative/Discussion and Vote (Public Meeting) (if needed)

Week of January 13—Tentative

Thursday, January 16

9:30 a.m.
Collegial Discussion of Items of Commissioner Interest (Public Meeting)
2:30 p.m.
Periodic Briefing on EEO Program (Public Meeting)

Friday, January 17

10:00 a.m.
Briefing on Status of Implementation of Safety Goal Policy Statement (Public Meeting)
11:30 a.m.
Affirmative/Discussion and Vote (Public Meeting) (if needed)
2:00 p.m.
Briefing on Progress of Research in the Area of Organization and Management (Public Meeting)

Note: Affirmation sessions are initially scheduled and announced to the public on a time-reserved basis. Supplementary notice is provided in accordance with the Sunshine Act as specific items are identified and added to the meeting agenda. If there is no specific subject listed for affirmation, this means that no item has as yet been identified as requiring any Commission vote on this date.

To verify the status of meeting call (recording)—(301) 504–1292.

CONTACT PERSON FOR MORE INFORMATION: William Hill (301) 504–1661.

Dated: December 19, 1991.

William M. Hill, Jr.,

Office of the Secretary.

[FR Doc. 91–30867 Filed 12–19–91; 2:39 pm]

BILLING CODE 7509–01–M

Corrections

Federal Register
Vol. 56, No. 247
Tuesday, December 24, 1991

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1205

[CN-91-003]

Amendment to the Cotton Research and Promotion Order

Correction

In rule document 91-29454, beginning on page 64470, in the issue of Tuesday, December 10, 1991, make the following correction:

§ 1205.324 [Corrected]

On page 64472, in the third column, in § 1205.324, in the last line, "The eligible" should be removed. On the following page (64473), the remainder of that sentence, consisting of the first six and 1/2 lines at the top of the page, should also be removed.

BILLING CODE 1505-01-D

DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Parts 1 and 2

[Docket No. 910373-1297]

RIN 0651-AA45

Revision of Patent and Trademark Fees

Correction

In rule document 91-29887, beginning on page 65142, in the issue of Friday, December 13, 1991, make the following corrections:

1. On page 65142, in the 3rd column, under *Statutory Provisions*, in the 17th line, "August 26," should read "August 27,".

2. On page 65145, in the first column, in the fourth full paragraph, in the fourth line, "of" should read "or".

3. On the same page, in the second column, in the first full paragraph, in the tenth line, "are" should read "and".

4. On the same page, in the third column, under *37 CFR 1.26 Refunds*, in the last line, "they" should read "the".

5. On page 65146, in the second column, under *37 CFR 2.6 Trademark Fees*, in the eighth line, "(c)-(l1)" should read "(c)-(l)".

6. On page 65150, in the third column, in the ninth full paragraph, in the ninth line, there should be a period after "title".

§ 1.12(d) [Corrected]

7. On page 65151, in the third column, in § 1.12(d), in the ninth line, "of" should read "or".

§ 2.6 [Corrected]

8. On page 65155, in the second column, in § 2.6(a)(15), in the first line, "of" should read "to".

9. On the same page, in the third column, in § 2.6(b)(4), in the third line, "(ii) Regular service" should read "(i) Regular service".

10. On the same page, in the same column, in § 2.6(b)(8), in the first line, remove the comma after "Marginal".

11. On page 65156, in the first column, in the first full paragraph, in the last line, "dates.)" should read "dates).".

BILLING CODE 1505-01-D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 91E-0357]

Determination of Regulatory Review Period for Purposes of Patent Extension; Survanta®

Correction

In notice document 91-27142 beginning on page 57525 in the issue of Tuesday, November 12, 1991, make the following corrections:

1. On page 57525, in the third column, in **SUPPLEMENTARY INFORMATION**, in the first paragraph, in the last line "and" should read "an".

2. On page 57526, in the first column, in the first full paragraph, in the eighth line, remove "of".

3. On the same page, in the second column, in the second paragraph, in the second line, "in" should read "is".

BILLING CODE 1505-01-D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 91M-0395]

Baxter Healthcare Corp.; Premarket Approval of the Carpentier-Edwards® Bioprosthesis Models 2625 (Aortic) and 6625 (Mitral)

Correction

In notice document 91-27145 appearning on page 57527 in the issue of Tuesday, November 12, 1991, make the following corrections:

1.In the second column, in the last paragraph, in the second line "360(d)(3)" should read "360e(d)(3)"

2. In the third column, in the last paragraph, in the third line, "3603(d)" should read "360e(d)".

BILLING CODE 1505-01-D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administraion

[Docket No.91E-0327]

Determination of Regulatory Review Period for Purposes of Patent Extension; Ventak® P AICD™ Model 1600

Correction

In notice document 91-27143 beginning on page 57529 in the issue of Tuesday, November 12, 1991, make the following corrections:

1. On page 57529, in the third column, in the subject heading in the third line, "Ventak®" was misspelled.

2. On page 57530, in the first column, in **SUPPLEMENTARY INFORMATION**, in the second paragraph, in the sixth line, "beings" should read "begins".

BILLING CODE 1505-01-D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Final Funding Priorities for Grants for Faculty Development in Family Medicine

Correction

In notice document 91-27219, beginning on page 57661, in the issue of Wednesday, November 13, 1991, make the following correction:

On page 57662, in the second column, in the file line at the end of the document, "FR Doc. 91-27214" should read "FR Doc. 91-27219".

BILLING CODE 1505-01-D

DEPARTMENT OF LABOR

Mine Safety and Health Administration

Petitions for Modification

Correction

In notice document 91-29386 appearing on page 64278 in the issue of Monday, December 9, 1991, make the following corrections:

1. In the second column, under entry 4, in the fourth line "74.213" should read "75.213".

2. In the same column, under entry 5, in the fourth line "74.202" should read "75.202".

BILLING CODE 1505-01-D

SECURITIES AND EXCHANGE COMMISSION

[Release No. IC-18397; 812-7670]

Boston Financial Tax Credit Fund Plus, a Limited Partnership, et al.; Application

Correction

In notice document 91-27095, beginning on page 57544, in the issue of Tuesday, November 12, 1991, make the following correction:

On page 57548, in the first column, in the file line at the end of the document, "FR Doc. 91-27025" should read "FR Doc. 91-27095".

BILLING CODE 1505-01-D

Federal Register

Tuesday
December 24, 1991

Part II

Department of Health and Human Services

Public Health Service; Office of the Assistant Secretary for Health; Agency for Health Care Policy and Research; Alcohol, Drug Abuse, and Mental Health Administration; National Institutes of Health; Centers for Disease Control; Agency for Toxic Substances and Disease Registry; Indian Health Service; Health Resources and Services Administration; and Food and Drug Administration

Privacy Act of 1974; Annual Publication of Systems of Records

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Office of the Assistant Secretary for Health

Privacy Act of 1974; Annual Publication of Systems of Records Notices

AGENCY: Public Health Service, HHS.

ACTION: Publication of minor changes to systems of records notices.

SUMMARY: In accordance with Office of Management and Budget Circular No. A–130, Appendix I, "Federal Agency Responsibilities for Maintaining Records About Individuals," the Office of the Assistant Secretary for Health (OASH) in the Public Health Service (PHS) has reviewed its system notices and determined that there are no changes.

SUPPLEMENTARY INFORMATION: OASH has completed the annual review of its systems of records. Since the publication of January 11, 1991, OASH has made no changes to its inventory of systems of records that affect the public's right or need to know. A Table of Contents of active systems of records is published below. The complete text of the system notices was last published in the Office of the Federal Register's 1989 biennial Compilation of Privacy Act Issuances.

Dated: October 21, 1991.

Wilford J. Forbush,

Director, Office of Management.

Office of the Assistant Secretary of Health

Table of Contents

[FR Doc. 91–25897 Filed 12–23–91; 8:45 am]
BILLING CODE 4160–17–M

Agency for Health Care Policy and Research

Privacy Act of 1974; Annual Publication of Systems of Records

AGENCY: Department of Health and Human Services (HHS); Public Health Services (PHS); Agency for Health Care Policy and Research (AHCPR).

ACTION: Annual Publication of Revisions to PHS Privacy Act System Notices.

SUMMARY: The Agency for Health Care Policy and Research (AHCPR) is publishing this notice in accordance with Office of Management and Budget Circular No. A–130, Appendix I, "Federal Agency Responsibilities for Maintaining Records About Individuals," which requires that agencies review each system of records annually and publish any minor changes in the **Federal Register.**

AHCPR has completed the annual review of its systems of records and is publishing below (1) a table of contents which lists all active systems of records in AHCPR, and (2) those minor changes which affect the public's right of need to know, such as changes in the system location of records or the address of system managers.

Dated: December 13, 1991.

J. Jarrett Clinton,

Administrator.

Table of Contents

09–35–0001

SYSTEM NAME:

Grants Record System, HHS/AHCPR/OM.

Minor changes have been made to this system notice. The following categories should be revised:

SYSTEM LOCATION:

Grants Management Branch, Office of Management, AHCPR, Executive Office Center, Suite 601, 2101 East Jefferson Street, Rockville, Maryland 20852–4993.

SYSTEM MANAGER AND ADDRESS:

Chief, Grants Management Branch, Executive Office Center, Suite 601, 2101 East Jefferson Street, Rockville, Maryland 20852–4993.

09–35–0002

SYSTEM NAME:

National Medical Expenditure Survey, HHS/AHCPR/CGHSIR.

Minor changes have been made to this system notice. The following categories should be revised:

SYSTEM LOCATION:

Division of Medical Expenditure Studies, Center for General Health Services Intramural Research, AHCPR, Executive Office Center, Suite 501, 2101 East Jefferson Street, Rockville, Maryland 20852–4993.

SYSTEM MANAGER AND ADDRESS:

Director, Division of Medical Expenditure Studies, Center for General Health Services Intramural Research, AHCPR, Executive Office Center, Suite 501, 2101 East Jefferson Street, Rockville, Maryland 20852–4993.

09–35–0003

SYSTEM NAME:

AIDS Cost and Service Utilization Survey (ACSUS), HHS/AHCPR/CGHSER.

Minor changes have been made to this system notice. The following categories should be revised:

SYSTEM LOCATION:

Division of Cost and Financing, Center for General Health Services Extramural Research, AHCPR, Executive Office Center, Suite 502, 2101 East Jefferson Street, Rockville, Maryland 20852–4993.

SYSTEM MANAGER AND ADDRESS:

Director, Division of Cost and Financing, Center for General Health Services Extramural Research, AHCPR, Executive Office Center, Suite 502, 2101 East Jefferson Street, Rockville, Maryland 20852–4993.

[FR Doc. 91–30494 Filed 12–23–91; 8:45 am]
BILLING CODE 4160–90

Alcohol, Drug Abuse, and Mental Health Administration

Privacy Act of 1974: Annual Publication of Revisions to PHS Privacy Act Systems Notices

AGENCY: Department of Health and Human Services (DHHS); Public Health Service (PHS); Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA).

ACTION: Privacy Act: Annual Publication of Revisions to Privacy Act System Notices.

SUMMARY: ADAMHA is publishing this document to meet the requirement of Section 3.a (8) of Appendix I to OMB Circular No. A–130, "Federal Responsibilities for Maintaining Records about Individuals," which requires that agencies review each system of records annually and publish any minor changes in the **Federal Register** (FR). ADAMHA has reviewed all of its active Privacy Act systems of records and is publishing the resulting revisions.

SUPPLEMENTARY INFORMATION: ADAMHA has completed the annual review of its systems or records' notices and is publishing below those minor changes which affect the public's right or need to know.

1. Changes:

The following minor changes have been made to systems of records as follows:

a. 09–30–0036

System Name:

Alcohol, Drug Abuse, and Mental Health Epidemiologic and Biometric Research Data, HHS/ADAMHA/OA.

System Manager(s) and Address:

Director, Division of Applied and Services Research, National Institutes of Mental Health, Room 18C–26, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857

Director, Division of Clinical Research, National Institutes of Mental Health, Room 10–105, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857

Director, Division of Biometry and Epidemiology, National Institute on Alcohol Abuse and Alcoholism, Room 14C–26, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland, 20857

Director, Division of Clinical and Prevention Research, National Institute on Alcohol Abuse and Alcoholism, Room 14C–10, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857

Director, Division of Clinical Research, National Institute on Drug Abuse, Room 10A–38, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857

Director, Division of Epidemiology and Prevention Research, National Institute on Drug Abuse, Suite 615, Rockwall II Building, 5600 Fishers Lane, Rockville, Maryland 20857

Director, Division of Applied Research, National Institute on Drug Abuse, Room 9A–54, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857

b. 09–30–0039

SYSTEM NAME:

Drug Abuse Treatment Outcome Study (DATOS), HHS/ADAMHA/NIDA.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Voluntary adult clients of federally funded treatment programs, including Treatment Alternative Street Crime (TASC) Programs of the Department of Justice, who requested to be included in TOPS from 1979 through 1986. New data collected from voluntary adult and juvenile (ages 12–18) clients of public and privately funded treatment programs beginning in 1991 and will continue through 1995.

2. Readers who notice any errors or omissions in the ADAMHA system of records' notices are invited to bring them to my attention at the following address: Alcohol, Drug Abuse, and Mental Health Administration, 5600 Fishers Lane, Room 12–105, Rockville, Maryland 20857.

Dated: November 4, 1991.

Joseph R. Leone,

Executive Officer, Alcohol, Drug Abuse, and Mental Health Administration.

3. Table of Contents

The following is a list of system notices which ADAMHA currently maintains:

09–30–0004 Intramural Research Program Records of Research Performed on In- and Out-Patients with Various Types of Mental Illness, HHS/ADAMHA/NIMH; publ. **Federal Register**, Vol. 48, No. 230, p. 53798.

09–30–0020 Patient Records on PHS Beneficiaries (1935–1974) and Civilly Committed Drug Abusers (1967–1978), HHS/ADAMHA/NIDA; publ. **Federal Register**, Vol. 49, No. 244, p. 49181.

09–30–0022 National Institute on Drug Abuse, Addiction Research Center, Federal Prisoner and Non-Prisoner Patient Files, HHS/ADAMHA/NIDA; publ. **Federal Register**, Vol. 48, No. 230; p. 53816.

09–30–0023 Records of Contracts Awarded to Individuals, HHS/ADAMHA/OA; publ. **Federal Register**, Vol. 49, No. 106, p. 22713.

09–30–0027 Grants and Cooperative Agreements: Research, Research Training, Research Scientist Development, Education, Demonstration, Fellowship, Clinical Training, Community Services, HHS/ADAMHA/OA; publ. **Federal Register**, Vol. 49, No. 106, p. 22714.

09–30–0029 Records of Guest Workers, HHS/ADAMHA/OA; publ. **Federal Register**, Vol. 48, No. 230, p. 53823.

09–30–0030 Records of Visiting Fellows, HHS/ADAMHA/OA; publ. **Federal Register**, Vol. 48, No. 230, p. 53824.

09–30–0033 Correspondence Files, HHS/ADAMHA/OA; publ. **Federal Register**, Vol. 48, No. 230, p. 53825.

09–30–0035 Three Mile Island Mental Health Survey Respondents Record, HHS/ADAMHA/NIMH; publ. **Federal Register**, Vol. 47, No. 198, p. 45459.

09–30–0036 Alcohol, Drug Abuse, and Mental Health Epidemiologic and Biometric Research Data HHS/ADAMHA/OA; publ. **Federal Register**, Vol. 49, No. 206, p. 42639.

09–30–0037 Psychotherapy of Opiate-Dependent Individuals, HHS/ADAMHA/NIDA; publ. **Federal Register**, Vol. 48, No. 230, p. 53828.

09–30–0038 Subject-Participants in Pharmacokinetic Studies on Drugs of Abuse, HHS/ADAMHA/NIDA; publ. **Federal Register**, Vol. 48, No. 230, p. 53829.

09–30–0039 Drug Abuse Treatment Outcome Study (DATOS) HHS/ADAMHA/NIDA; publ. **Federal Register**, Vol. 48, No. 230, p. 53830 and **Federal Register**, Vol. 54, No. 221, p. 47865.

09–30–0041 Subject-Participants in Drug Abuse Research Studies Supporting New Drug Applications, HHS/ADAMHA/NIDA; publ. **Federal Register**, Vol. 48, No. 112, p. 26672.

09–30–0043 Shipment Records of Drugs of Abuse to Authorized Researchers, HHS/ADAMHA/NIDA; publ. **Federal Register**, Vol. 48, No. 230, p. 53832.

09–30–0047 Patient Records on Chronic Mentally Ill Merchant Seamen Treated at Nursing Homes in Lexington, Kentucky, (1942 to Present), HHS/ADAMHA/NIMH; publ. **Federal Register**, Vol. 51, No. 226, p. 42395.

09–30–0048 Intramural Research Program Records of In- and Out-Patients With Various Types of Alcohol Abuse and Dependence, Relatives of Patients With Alcoholism, and Healthy Volunteers, HHS/ADAMHA/NIAAA; publ. **Federal Register**, Vol. 51, No. 226, p. 42396.

09–30–0049 Consultant Records Maintained by ADAMHA Contractors, HHS/ADAMHA/OA; publ. **Federal Register**, Vol. 52, No. 195, p. 37660.

09–30–0050 Clinical Research: Patient Medical Records, HHS/ADAMHA/NIMH; publ. **Federal Register**, Vol. 53, No. 81, p. 15142.

[FR Doc. 91–27463 Filed 12–23–91; 8:45 am]

BILLING CODE 4160–20

National Institutes of Health

Privacy Act of 1974; Annual Publication of Systems of Records

AGENCY: Public Health Service, DHHS.

ACTION: Privacy Act: Annual republication of notices of revised systems of records.

SUMMARY: The National Institutes of Health (NIH) has conducted a comprehensive review of all Privacy Act systems of records and is publishing the

resulting revisions. None of the revisions meet the OMB criteria for a new or altered system of records requiring an advance period for public comment. These changes are in compliance with Circular A–130, Appendix 1. The notices republished below are complete and accurate as of November 1, 1991.

SUPPLEMENTARY INFORMATION: The following information summarizes the current status of systems of records which had minor modifications during 1991 and lists all systems maintained by NIH:

A. SYSTEM NAME.

The following system has been updated to reflect a change in the name of the system:

09–25–0036, Extramural Awards: IMPAC (Grant/Contract/Cooperative Agreement Information), HHS/NIH/DRG.

B. SYSTEM LOCATION.

The following systems have been updated to reflect a change in the system locations. These changes do not affect the access by the individual to the individual's records.

09–25–0033, International Activities: Fellowships Awarded by Foreign Organizations, HHS/NIH/FIC.
09–25–0035, International Activities: Health Scientist Exchange Programs, HHS/NIH/FIC.
09–25–0060, Clinical Research: Division of Cancer Treatment Clinical Investigations, HHS/NIH/NCI.
09–25–0069, NIH Clinical Center Admissions of the National Cancer Institute, HHS/NIH/NCI.
09–25–0112, Grants and Cooperative Agreements: Research, Research Training, Fellowship and Construction Applications and Related Awards, HHS/NIH/OD.
09–25–0115, Administration: Curricula Vitae of Consultants and Clinical Investigators, HHS/NIH/NIAID.
09–25–0118, Contracts: Professional Services Contractors, HHS/NIH/NCI.
09–25–0121, International Activities: Senior International Fellowships Program, HHS/NIH/FIC.
09–25–0151, Administration: Public Health Service ALERT Records Concerning Individuals Under Investigation for Possible Misconduct in Science or Subject to Sanctions for Such Misconduct, HHS/PHS/NIH.
09–25–0165, National Institutes of Health Acquired Immunodeficiency Syndrome (AIDS) Research Loan Repayment Program, HHS/NIH/OD.

C. CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM.

There are no changes in this category.

D. CATEGORIES OF RECORDS.

The following system has been updated to reflect a change in the categories of records in the system. This change does not alter the character or purpose of the system.

09–25–0124, Administration: Pharmacology Research Associates, HHS/NIH/NIGMS.

E. AUTHORITY.

There are no changes in this category.

F. STORAGE.

The following systems have been updated to reflect a change in the method of storing the records:

09–25–0077, Biological Carcinogenesis Branch Human Specimen Program, HHS/NIH/NCI.
09–25–0140, International Activities: International Scientific Researchers in Intramural Laboratories at the National Institutes of Health, HHS/NIH/FIC.

G. RETRIEVAL.

The following system has been updated to reflect a change or clarification in the method of retrieving the records.

09–25–0140, International Activities: International Scientific Researchers in Intramural Laboratories at the National Institutes of Health, HHS/NIH/FIC.

H. SAFEGUARDS.

The following system has been updated to reflect a change in the safeguards:

09–25–0140, International Activities: International Scientific Researchers in Intramural Laboratories at the National Institutes of Health, HHS/NIH/FIC.

I. RETENTION AND DISPOSAL.

There are no changes in this category.

J. SYSTEM MANAGER(S) AND ADDRESS(ES).

The following systems have been updated to reflect a change in the system manager or the address of the system manager. These changes do not affect the access by the individual to the individual's records.

09–25–0010, Research Resources: Registry of Individuals Potentially Exposed to Microbial Agents, HHS/NIH/NCI.
09–25–0016, Clinical Research: Collaborative Perinatal Project, HHS/NIH/NINDS.
09–25–0028, Clinical Research: Patient Medical Histories, HHS/NIH/NINDS and HHS/NIH/NIDCD.
09–25–0033, International Activities: Fellowships Awarded by Foreign Organizations, HHS/NIH/FIC.
09–25–0035, International Activities: Health Scientist Exchange Programs, HHS/NIH/FIC.
09–25–0054, Administration: Property Accounting, HHS/NIH/ORS.
09–25–0060, Clinical Research: Division of Cancer Treatment Clinical Investigations, HHS/NIH/NCI.
09–25–0069, NIH Clinical Center Admissions of the National Cancer Institute, HHS/NIH/NCI.
09–25–0077, Biological Carcinogenesis Branch Human Specimen Program, HHS/NIH/NCI.
09–25–0091, Administration: General Files on Employees, Donors and Correspondents, HHS/NIH/NEI.
09–25–0112, Grants and Cooperative Agreements: Research, Research Training, Fellowship and Construction Applications and Related Awards, HHS/NIH/OD.
09–25–0115, Administration: Curricula Vitae of Consultants and Clinical Investigators, HHS/NIH/NIAID.
09–25–0118, Contracts: Professional Services Contractors, HHS/NIH/NCI.
09–25–0121, International Activities: Senior International Fellowships Program, HHS/NIH/FIC.
09–25–0129, Clinical Research: Clinical Research Studies dealing with Hearing, Speech, Language and Chemosensory Disorders, HHS/NIH/NIDCD.
09–25–0142, Clinical Research: Records of Subjects in Intramural Research, Epidemiology, Demography and Biometry Studies on Aging, HHS/NIH/NIA.
09–25–0143, Biomedical Research: Records of Subjects in Clinical, Epidemiologic and Biometric Studies of the National Institute of Allergy and Infectious Diseases, HHS/NIH/NIAID.
09–25–0148, Contracted and Contract-Related Research: Records of Subjects in Clinical, Epidemiological and Biomedical Studies of the National Institute of Neurological Disorders and Stroke and the National Institute on Deafness and Other Communication Disorders, HHS/NIH/NINDS and HHS/NIH/NIDCD.
09–25–0151, Administration: Public Health Service ALERT Records Concerning Individuals Under Investigation for Possible Misconduct in Science or Subject to Sanctions for Such Misconduct, HHS/PHS/NIH.
09–25–0156, Records of Participants in Programs and Respondents in Surveys Used to Evaluate Programs of the National Institutes of Health, HHS/NIH/OD.
09–25–0161, Administration: NIH Consultant File, HHS/NIH/DRG.
09–25–0165, National Institutes of Health Acquired Immunodeficiency Syndrome (AIDS) Research Loan Repayment Program, HHS/NIH/OD.

K. RECORD ACCESS.

The following system has been updated to reflect a change in the record access procedures.

09–25–0112, Grants and Cooperative Agreements: Research, Research Training, Fellowship and Construction Applications and Related Awards, HHS/NIH/OD.

L. NOTIFICATION PROCEDURES.

The following systems have been updated to reflect a change in the office, official, and/or address to write to to determine whether or not the system contains a record about the individual.

09–25–0028, Clinical Research: Patient Medical Histories, HHS/NIH/NINDS and HHS/NIH/NIDCD.
09–25–0046, Clinical Research: Catalog of Clinical Specimens from Patients,

Volunteers and Laboratory Personnel, HHS/NIH/NIAID.
09–25–0048, Clinical Research: Serology-Epidemiology Parasite Research, HHS/NIH/NIAID.
09–25–0087, Administration: Employees and Consultants, HHS/NIH/NIAID.
09–25–0115, Administration: Curricula Vitae of Consultants and Clinical Investigators, HHS/NIH/NIAID.
09–25–0143, Biomedical Research: Records of Subjects in Clinical, Epidemiologic and Biometric Studies of the National Institute of Allergy and Infectious Diseases, HHS/NIH/NIAID.
09–25–0129, Clinical Research: Clinical Research Studies dealing with Hearing, Speech, Language and Chemosensory Disorders. HHS/NIH/NIDCD.
09–25–0148, Contracted and Contract-Related Research: Records of Subjects in Clinical, Epidemiological and Biomedical Studies of the National Institute of Neurological Disorders and Stroke and the National Institute on Deafness and Other Communication Disorders, HHS/NIH/NINDS and HHS/NIH/NIDCD.

M. THE FOLLOWING SYSTEMS HAVE BEEN CHANGED FOR CLARITY AND EDITING PURPOSES.

In addition, the language in the sections on Safeguards, Record Access Procedure, and Contesting Record Procedure for the systems listed in the Table of Contents has been edited to improve the clarity and specificity of the system notice and/or to incorporate standardized language to achieve uniformity.

09–25–0001, Clinical Research: Patient Records, HHS/NIH/NHLBI.
09–25–0011, Clinical Research: Blood Donor Records, HHS/NIH/CC.
09–25–0012, Clinical Research: Candidate Normal Volunteer Records, HHS/NIH/CC.
09–25–0016, Clinical Research: Collaborative Perinatal Project, HHS/NIH/NINDS.
09–25–0026, Clinical Research: Nervous System Studies, HHS/NIH/NINDS.
09–25–0028, Clinical Research: Patient Medical Histories, HHS/NIH/NINDS and HHS/NIH/NIDCD.
09–25–0031, Clinical Research: Serological and Virus Data in Studies Related to the Central Nervous System, HHS/NIH/NINDS.
09–25–0037, Clinical Research: Baltimore Longitudinal Study of Aging, HHS/NIH/NIA.
09–25–0038, Clinical Research: Patient Data, HHS/NIH/NIDDK.
09–25–0039, Clinical Research: Diabetes Mellitus Research Study of Southwestern American Indians, HHS/NIH/NIDDK.
09–25–0040, Clinical Research: Southwestern American Indian Patient Data, HHS/NIH/NIDDK.
09–25–0042, Clinical Research: National Institute of Dental Research Patient Records, HHS/NIH/NIDR.
09–25–0044, Clinical Research: Sensory Testing Research Program, HHS/NIH/NIDR.
09–25–0046, Clinical Research: Catalog of Clinical Specimens from Patients, Volunteers and Laboratory Personnel, HHS/NIH/NIAID.
09–25–0048, Clinical Research: Serology-Epidemiology Parasite Research, HHS/NIH/NIAID.
09–25–0053, Clinical Research: Vision Studies, HHS/NIH/NEI.
09–25–0099, Clinical Research: Patient Medical Records, HHS/NIH/CC.
09–25–0100, Clinical Research: Neuropharmacology Studies, HHS/NIH/NINDS.
09–25–0108, Personnel: Guest Researchers/Student Scientists/Special Volunteers/Scientists Emeriti, HHS/NIH/DPM.
09–25–0112, Grants and Cooperative Agreements: Research, Research Training, Fellowship and Construction Applications and Related Awards, HHS/NIH/OD.
09–25–0124, Administration: Pharmacology Research Associates, HHS/NIH/NIGMS.
09–25–0133, Clinical Research: Kidney Transplant Histocompatibility Study (KTHS), HHS/NIH/NIAID.
09–25–0153, Biomedical Research: Records of Subjects in Biomedical and Behavioral Studies of Child Health and Human Development, HHS/NIH/NICHD.

N. ORGANIZATION NAME CHANGE.

There are no changes in this category.

O. DELETED SYSTEMS OF RECORDS.

The following systems of records which appeared in the 1990 annual publication are now being deleted because:

09–25–0002, Clinical Research: Patient Phonocardiogram Records, HHS/NIH/NHLBI.

The technology (phonocardiography) used in this research study is no longer in use in the NHLBI; all records have been destroyed.

09–25–0003, Administration: Authorized Radionuclide Users File, HHS/NIH/ORS and 09–25–0008, Administration: Radiation Workers Monitoring, HHS/NIH/ORS.

These systems were consolidated into a single automated system 09–25–0166 title published in the **Federal Register** on September 26, 1991, Vol. 56, No. 187, p 48806.

09–25–0133, Clinical Research: Kidney Transplant Histocompatibility Study (KTHS), HHS/NIH/NIAID.

The study for which the system was established had been completed and the records were no longer required. The records have been destroyed in compliance with the NIH Records Control Schedule.

The following four systems that add a new routine use concerning the disclosure of information that an individual is infected with the human immunodeficiency virus (HIV) under certain limited circumstances were inadvertently omitted from the 1990 annual publication. This new routine use was published in the **Federal Register**, as noted, and incorporated into these systems, as follows:

09–25–0001, Clinical Research: Patient Records, HHS/NIH/NHLBI, publ. **Federal Register**, Vol. 55, Number 101, May 24, 1990.
09–25–0011, Clinical Research: Blood Donor Records, HHS/NIH/CC, publ. **Federal Register**, Vol. 55, Number 101, May 24, 1990.
09–25–0069, NIH Clinical Center Admissions of the National Cancer Institute, HHS/NIH/NCI, publ. **Federal Register**, Vol. 55, Number 101, May 24, 1990.
09–25–0099, Clinical Research: Patient Medical Records, HHS/NIH/CC, publ. **Federal Register**, Vol. 55, Number 101, May 24, 1990.

The following is a list of active systems of records maintained by NIH.

Table of Contents.

09–25–0034, International Activities: Scholars-in-Residence Program, HHS/NIH/FIC, publ. **Federal Register**, Vol. 56, No. 8, January 11, 1991.
09–25–0035 International Activities: Health Scientist Exchange Programs, HHS/NIH/FIC, publ. **Federal Register**, Vol. 56, No. 8, January 11, 1991.
09–25–0036, Extramural Awards: IMPAC (Grant/Contract/Cooperative Agreement Information), HHS/NIH/DRG, publ. **Federal Register**, Vol. 56, No. 8, January 11, 1991.
09–25–0037, Clinical Research: The Baltimore Longitudinal Study of Aging, HHS/NIH/NIA, publ. **Federal Register**, Vol. 56, No. 8, January 11, 1991.
09–25–0038, Clinical Research: Patient Data, HHS/NIH/NIDDK, publ. **Federal Register**, Vol. 56, No. 8, January 11, 1991.
09–25–0039, Clinical Research: Diabetes Mellitus Research Study of Southwestern American Indians, HHS/NIH/NIDDK, publ. **Federal Register**, Vol. 56, No. 8, January 11, 1991.
09–25–0040, Clinical Research: Southwestern American Indian Patient Data, HHS/NIH/NIDDK, publ. **Federal Register**, Vol. 56, No. 8, January 11, 1991.
09–25–0041, Research Resources: Scientists Requesting Hormone Distribution, HHS/NIH/NIDDK, publ. **Federal Register**, Vol. 56, No. 8, January 11, 1991.
09–25–0042, Clinical Research: National Institute of Dental Research Patient Records, HHS/NIH/NIDR, publ. **Federal Register**, Vol. 56, No. 8, January 11, 1991.
09–25–0044, Clinical Research: Sensory Testing Research Program, HHS/NIH/NIDR, publ. **Federal Register**, Vol. 56, No. 8, January 11, 1991.
09–25–0046, Clinical Research: Catalog of Clinical Speciments from Patients, Volunteers and Laboratory Personnel, HHS/NIH/NIAID, publ. **Federal Register**, Vol. 56, No. 8, January 11, 1991
09–25–0048, Clinical Research: Serology-Epidemiology Parasite Research, HHS/NIH/NIAID, publ. **Federal Register**, Vol. 56, No. 8, January 11, 1991.
09–25–0053, Clinical Research: Vision Studies, HHS/NIH/NEI, publ. **Federal Register**, Vol. 56, No. 8, January 11, 1991.
09–25–0054, Administration: Property Accounting, HHS/NIH/ORS, publ. **Federal Register**, Vol. 56, No. 8, January 11, 1991.
09–25–0057, Clinical Research: Burkitt's Lymphoma Registry, HHS/NIH/NCI, publ. **Federal Register**, Vol. 56, No. 8, January 11, 1991.
09–25–0060, Clinical Research: Division of Cancer Treatment Clinical Investigations, HHS/NIH/NCI, publ. **Federal Register**, Vol. 56, No. 8, January 11, 1991.
09–25–0067, Clinical Research: National Cancer Incidence Surveys, HHS/NIH/NCI, publ. **Federal Register**, Vol. 56, No. 8, January 11, 1991.
09–25–0069, NIH Clinical Center Admissions of the National Cancer Institute, HHS/NIH/NCI, publ. **Federal Register**, Vol. 55, Number 101, May 24, 1990.
09–25–0074, Clinical Research: Division of Cancer Biology and Diagnosis Patient Trials, HHS/NIH/NCI, publ. **Federal Register**, Vol. 56, No. 8, January 11, 1991.
09–25–0075, Administration: Institutions Submitting Assurances for Protection from Research Risks and Animal Welfare, HHS/NIH/OD/OER, publ. **Federal Register**, Vol. 56, No. 8, January 11, 1991.
09–25–0077, Biological Carcinogenesis Branch Human Specimen Program, HHS/NIH/NCI, publ. **Federal Register**, Vol. 56, No. 8, January 11, 1991.
09–25–0078, Administration: Consultant File, HHS/NIH/NHLBI, publ. **Federal Register**, Vol. 56, No. 8, January 11, 1991.
09–25–0087, Administration: Employees and Consultants, HHS/NIH/NIAID, publ. **Federal Register**, Vol. 56, No. 8, January 11, 1991.
09–25–0091, Administration: General Files on Employees, Donors and Correspondents, HHS/NIH/NEI, publ. **Federal Register**, Vol. 56, No. 8, January 11, 1991.
09–25–0093, Administration: Administration Authors, Reviewers and Members of the Journal of the National Cancer Institute, HHS/NIH/NCI, publ. **Federal Register**, Vol. 56, No. 8, January 11, 1991.
09–25–0096, Contracts: National Cancer Institute Contract Management System Principal Investigators, Project Officers and Contract Specialists, HHS/NIH/NCI, publ. **Federal Register**, Vol. 56, No. 8, January 11, 1991.
09–25–0099, Clinical Research: Patient Medical Records, HHS/NIH/CC, publ. **Federal Register**, Vol. 55, Number 101, May 24, 1990.
09–25–0100, Clinical Research: Neuropharmacology Studies, HHS/NIH/NINDS, publ. **Federal Register**, Vol. 56, No. 8, January 11, 1991.
09–25–0102, Administration: Grants Associates Program Working Files, HHS/NIH/DRG, publ. **Federal Register**, Vol. 56, No. 8, January 11, 1991.
09–25–0105, Administration: Health Records of Employees, Visiting Scientists, Fellows, Contractors and Relatives of Inpatients, HHS/NIH/OD, publ. **Federal Register**, Vol. 56, No. 8, January 11, 1991.
09–25–0106, Administration: Executive Secretariat Correspondence Records, HHS/NIH/OD, publ. **Federal Register**, Vol. 56, No. 8, January 11, 1991.
09–25–0108, Personnel: Guest Researchers/Student Scientists/Special Volunteers/Scientists Emeriti, HHS/NIH/DPM, publ. **Federal Register**, Vol. 56, No. 8, January 11, 1991.
09–25–0112, Grants and Cooperative Agreements: Research, Research Training, Fellowship and Construction Applications and Related Awards, HHS/NIH/OD, publ. **Federal Register**, Vol. 56, No. 8, January 11, 1991.
09–25–0115, Administration: Curricula Vitae of Consultants and Clinical Investigators, HHS/NIH/NIAID, publ. **Federal Register**, Vol. 56, No. 8, January 11, 1991.
09–25–0118, Contracts: Professional Services Contractors, HHS/NIH/NCI, publ. **Federal Register**, Vol. 56, No. 8, January 11, 1991.
09–25–0121, International Activities: Senior International Fellowships Program, HHS/NIH/FIC, publ. **Federal Register**, Vol. 56, No. 8, January 11, 1991.
09–25–0124, Administration: Pharmacology Research Associates, HHS/NIH/NIGMS, publ. **Federal Register**, Vol. 56, No. 8, January 11, 1991.
09–25–0126, Clinical Research: National Heart, Lung, and Blood Institute Epidemiological and Biometric Studies, HHS/NIH/NHLBI, publ. **Federal Register**, Vol. 56, No. 8, January 11, 1991.
09–25–0128, Clinical Research: Neural Prosthesis and Biomedical Engineering Studies, HHS/NIH/NINDS, publ. **Federal Register**, Vol. 56, No. 8, January 11, 1991.
09–25–0129, Clinical Research: Clinical Research Studies Dealing with Hearing, Speech, Language and Chemosensory Disorders, HHS/NIH/NIDCD, publ. **Federal Register**, Vol. 56, No. 8, January 11, 1991.
09–25–0130, Clinical Research: Studies in the Division of Cancer Cause and Prevention, HHS/NIH/NCI, publ. **Federal Register**, Vol. 56, No. 8, January 11, 1991.
09–25–0134, Clinical Research: Epidemiology Studies, National Institute of Environmental Health Sciences, HHS/NIH/NIEHS, publ. **Federal Register**, Vol. 56, No. 8, January 11, 1991.
09–25–0140, International Activities: International Scientific Researchers in Intramural Laboratories at National Institutes of Health, HHS/NIH/FIC, publ. **Federal Register**, Vol. 56, No. 8, January 11, 1991.
09–25–0142, Clinical Research: Records of Subjects in Intramural Research, Epidemiology, Demography and Biometry Studies on Aging, HHS/NIH/NIA, publ. **Federal Register**, Vol. 56, No. 8, January 11, 1991.
09–25–0143, Biomedical Research: Records of Subjects in Clinical, Epidemiologic and Biometric Studies of the National Institute of Allergy and Infectious Diseases, HHS/NIH/NIAID, publ. **Federal Register**, Vol. 56, No. 8, January 11, 1991.
09–25–0145, Clinical Trials and Epidemiological Studies Dealing with Visual Disease and Disorders in the National Eye Institute, HHS/NIH/NEI, publ. **Federal Register**, Vol. 56, No. 8, January 11, 1991.
09–25–0148, Contracted and Contract-Related Research: Records of Subjects in Clinical, Epidemiological and Biomedical Studies of the National Institute of Neurological Disorders and Stroke and the National Institute on Deafness and Other Communication Disorders, HHS/NIH/NINDS and HHS/NIH/NIDCD, publ. **Federal Register**, Vol. 56, No. 8, January 11, 1991.
09–25–0151, Administration: Public Health Service ALERT Records Concerning Individuals Under Investigation for Possible Misconduct In Science or Subject to Sanctions for Such Misconduct, HHS/PHS/NIH, publ. **Federal Register**, Vol. 56, No. 8, January 11, 1991.
09–25–0152, Biomedical Research: Records of Subjects in National Institute of Dental Research Contracted Epidemiological and Biometric Studies, HHS/NIH/NIDR, publ. **Federal Register**, Vol. 56, No. 8, January 11, 1991.
09–25–0153, Biomedical Research: Records of Subjects in Biomedical and Behavioral Studies of Child Health and Human

Development, HHS/NIH/NICHD, publ. **Federal Register**, Vol. 56, No. 8, January 11, 1991.

09–25–0154, Biomedical Research: Records of Subjects in Cancer Studies of the Division of Cancer Prevention and Control, HHS/NIH/NCI, publ. **Federal Register**, Vol. 56, No. 8, January 11, 1991.

09–25–0156, Records of Participants in Programs and Respondents in Surveys Used to Evaluate Programs of the National Institutes of Health, HHS/NIH/OD, publ. **Federal Register**, Vol. 56, No. 8, January 11, 1991.

09–25–0158, Administration: Records of Applicants and Awardees of the NIH Intramural Research Training Awards Program, HHS/NIH/OD, publ. **Federal Register**, Vol. 56, No. 8, January 11, 1991.

09–25–0160, United States Renal Data System (USRDS), HHS/NIH/NIDDK publ. **Federal Register**, Vol. 56, No. 8, January 11, 1991.

09–25–0161, Administration: NIH Consultant File, HHS/NIH/DRG publ. **Federal Register**, Vol. 56, No. 8, January 11, 1991.

09–25–0165, National Institutes of Health Acquired Immunodeficiency Syndrome (AIDS) Research Loan Repayment Program, HHS/NIH/OD, publ. **Federal Register**, August 5, 1991, Vol. 56, No. 150, p. 37223.

09–25–0166, Administration: Radiation Safety Information, HHS/NIH/ORS, publ. **Federal Register**, September 26, 1991, Vol. 56, No. 187, p. 48806.

Dated: December 12, 1991.

Bernadine P. Healy,

Director, National Institutes of Health.

09–25–0001

SYSTEM NAME:

Clinical Research: Patient Records, HHS/NIH/NHLBI.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

National Institutes of Health, Building 10, 9000 Rockville Pike, Bethesda, MD 20892.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Patients of the National Heart, Lung, and Blood Institute (NHLBI) under study at the National Institutes of Health (NIH).

CATEGORIES OF RECORDS IN THE SYSTEM:

Medical histories, diagnostic studies, laboratory data, treatment.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 U.S.C. 241(e), 287, 287a.

PURPOSE(S):

(1) For use by physicians in evaluation and treatment of patients under study at NIH. (2) To furnish patient data to patients, their families, and with patients' consent, to their private physicians.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USE:

1. Clinical research data are made available to approved or collaborating researchers, including HHS contractors and grantees.

2. Certain diseases and conditions, including infectious diseases, may be reported to appropriate representatives of State or Federal Government as required by State or Federal law.

3. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example in defending against a claim based upon an individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, the Department may disclose such records as it deems desirable or necessary to the Department of Justice or other appropriate Federal agency to enable that agency to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

4. (a). PHS may inform the sexual and/or needle-sharing partner(s) of a subject individual who is infected with the human immunodeficiency virus (HIV) of their exposure to HIV, under the following circumstances: (1) The information has been obtained in the course of clinical activities at PHS facilities carried out by PHS personnel or contractors; (2) The PHS employee or contractor has made reasonable efforts to counsel and encourage the subject individual to provide the information to the individual's sexual or needle-sharing partner(s); (3) The PHS employee or contractor determines that the subject individual is unlikely to provide the information to the sexual or needle-sharing partner(s) or that the provision of such information cannot reasonably be verified; and (4) The notification of the partner(s) is made, whenever possible, by the subject individual's physician or by a professional counselor and shall follow standard counseling practices.

(b). PHS may disclose information to State or local public health departments, to assist in the notification of the subject individual's sexual and/or needle-sharing partner(s), or in the verification that the subject individual has notified such sexual or needle-sharing partner(s).

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

File folders, card index, laboratory books, computer memory.

RETRIEVABILITY:

Indexed by name or patient number.

SAFEGUARDS:

Measures to prevent unauthorized disclosures are implemented as appropriate for each location. Each site implements personnel, physical, and procedural safeguards such as the following:

1. Authorized Users: Employees who maintain records in this system are instructed to grant regular access only to authorized physicians and their assistants.

2. Physical Safeguards: Records are kept in secure locked metal or wood file cabinets and, in some instances, in locked offices.

3. Procedural Safeguards: Access to files is strictly controlled by files staff. Access to computerized records is controlled by keyword codes available only to authorized users.

These practices are in compliance with the standards of Chapter 45–13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45–13, and Part 6, "ADP Systems Security," of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 3000–G–3, which allows records to be kept as long as they are useful in scientific research. Refer to the NIH Manual Chapter for specific conditions on disposal.

SYSTEM MANAGER(S) AND ADDRESS:

National Heart, Lung, and Blood Institute, Administrative Officer, Division of Intramural Research, Building 10 Room 7N218, 9000 Rockville Pike, Bethesda, MD 20892.

NOTIFICATION PROCEDURE:

To determine if a record exists, contact: National Institutes of Health, Privacy Act Coordinator, NHLBI, Building 31, Room 5A08, 9000 Rockville Pike, Bethesda, MD 20892.

An individual who requests notification of or access to a medical record shall, at the time the request is made, designate in writing, a responsible representative, who may be a physician, who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

RECORDS ACCESS PROCEDURE:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Contact the official under notification procedures above, and specify the information to be contested, the corrective action sought, and the reasons for the correction, with supporting justification. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Referring physicians, hospitals and medical centers, patients and families, results of procedures and tests of NIH patients.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09-25-0005

SYSTEM NAME:

Administration: Library Operations and User I.D. File, HHS/NIH/OD.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

This system of records is an umbrella system comprising separate sets of records located in National Institutes of Health (NIH) facilities in Bethesda, Maryland, or facilities of contractors of the NIH. Write to the appropriate system manager listed below for list of current contractor locations.

National Institutes of Health, Building 10, Room 1L07, 9000 Rockville Pike, Bethesda, MD 20892,
and
National Institutes of Health, Building 12A, Room 3018, 9000 Rockville Pike, Bethesda, MD 20892,
and
National Institutes of Health, Building 38, Room 1S33, 8600 Rockville Pike, Bethesda, MD 20894,
and
National Institutes of Health, Building 38A, Room 4N419, 8600 Rockville Pike, Bethesda, MD 20894,
and
National Technical Information Service, Accounting Department, 8001 Forbes Place, Room 208F, Springfield, Virginia 22151.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Users of Library Services.

CATEGORIES OF RECORDS IN THE SYSTEM:

Name, organization, address, phone number, user code and identification number; and when applicable, credit card number and billing information.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Section 301 of the Public Health Service Act, describing the general powers and duties of the Public Health Service relating to research and investigation (42 U.S.C. 241).

PURPOSE OF THE SYSTEM:

To monitor library material, services, and circulation control; to provide user documentation; and to provide billing information to the National Technical Information Service (NTIS).

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

2. The Department of Health and Human Services (HHS) may disclose information from this system of records to the Department of Justice, or to a court or other tribunal, when (a) HHS, or any component thereof; or (b) any HHS employee in his or her official capacity; or (c) any HHS employee in his or her individual capacity where the Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the employee; or (d) the United States or any agency thereof where HHS determines that the litigation is likely to affect HHS or any of its components, is a party to litigation or has an interest in such litigation, and HHS determines that the use of such records by the Department of Justice, court or other tribunal is relevant and necessary to the litigation and would help in the effective representation of the governmental party, provided, however that in each case, HHS determines that such disclosure is compatible with the purpose for which the records were collected.

3. Disclosure may be made to contractors and staff to monitor library material, services, circulation control; to provide user documentation; and to process or refine the records. Recipients are required to maintain Privacy Act safeguards with respect to those records.

4. Disclosure may be made to the NTIS for billing individuals for certain library services.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored on computer tape and disc, microfiche, paper and file cards.

RETRIEVABILITY:

Records are retrieved by name, user code and/or identification number.

SAFEGUARDS:

1. Authorized Users: Employees who maintain records in this system are instructed to grant regular access only to Library staff members who need to verify that Library identification cards have been issued to those Library users requesting services such as MEDLINE and other computer online bibliographic searches, translations and interlibrary loans. Other one-time and special access by other employees is granted on a need-to-know basis as specifically authorized by the system manager. The contractor maintains a list of personnel having authority to access records to perform their duties.

2. Physical Safeguards: The offices housing the cabinets and file drawers for storage of records are locked during all library off-duty hours. During all duty hours offices are attended by employees who maintain the files. The contractor has secured records storage areas which are not left unattended during the working hours and file cabinets which are locked after hours.

3. Procedural Safeguards: Access to the file is strictly controlled by employees who maintain the files. Records may be removed from files only at the request of the system manager or other authorized employees. Access to computerized records is controlled by the use of security codes known only to authorized users. Contractor personnel receive instruction concerning the significance of safeguards under the Privacy Act.

These practices are in compliance with the standards of Chapter 45–13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45–13, and Part 6, "ADP Systems Security," of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 8000–D–2, which allows records to be kept until superseded or for a maximum period of 6 years. Refer to the NIH Manual Chapter for specific conditions on disposal.

SYSTEM MANAGER AND ADDRESS:

The Policy Coordinating Official for this system is the Management Analyst, Office of Administration; National Library of Medicine; Building 38, Room 2N21; 8600 Rockville Pike; Bethesda, MD 20894.

Chief, Reference and Bibliographic Services Section, Library Branch, National Center for Research Resources, National Institutes of Health, Building 10, Room 1L21, 9000 Rockville Pike, Bethesda, MD 20892,
and
Librarian, Division of Computer Research and Technology, National Institutes of Health, Building 12A, Room 3018, 9000 Rockville Pike, Bethesda, MD 20892,
and
Chief, Public Services Division, Library Operations, National Library of Medicine, National Institutes of Health, Building 38, Room 1S33, 8600 Rockville Pike, Bethesda, MD 20894,
and
Chief, Medlars Management Section, Bibliographic Services Division, Library Operations, National Institutes of Health, National Library of Medicine, Building 38A, Room 4N419, 8600 Rockville Pike, Bethesda, MD 20894.

NOTIFICATION PROCEDURE:

Write to the System Manager to determine if a record exists. The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

RECORD ACCESS PROCEDURE:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request an accounting of disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Write to the official at the address specified under notification procedures above, and reasonably identify the record and specify the information to be contested, the corrective action sought, and the reasons for the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Individual, NIH Library ID card data.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09–25–0010

SYSTEM NAME:

Research Resources: Registry of Individuals Potentially Exposed to Microbial Agents, HHS/NIH/NCI.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

National Institutes of Health, Executive Plaza North, Room 540, 6130 Executive Blvd., Bethesda, MD 20892.

Write to System Manager at the address below for the address of the Federal Records Center where records from this system may be stored.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals potentially exposed to biohazardous microbial agents.

CATEGORIES OF RECORDS IN THE SYSTEM:

Microbial agents registry.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 U.S.C. 241.

PURPOSE OF THE SYSTEM:

(1) To serve as a base for health and safety for individuals and organizations involved in use of potentially hazardous agents. (2) To identify potential hazards.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

2. The Department of Health and Human Services (HHS) may disclose information from this system of records to the Department of Justice, or to a court or other tribunal, when (a) HHS, or any component thereof; or (b) any HHS employee in his or her official capacity; or (c) any HHS employee in his or her individual capacity where the Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the employee; or (d) the United States or any agency thereof where HHS determines that the litigation is likely to affect HHS or any of its components, is a party to litigation or has any interest in such litigation, and HHS determines that the use of such records by the Department of Justice, court or other tribunal is relevant and necessary to the litigation and would help in the effective representation of the governmental party, provided, however that in each case, HHS determines that such disclosure is compatible with the purpose for which the records were collected.

POLICIES AND PRACTICES FOR STORAGE, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored in file folders, on magnetic tape, and 3380 disks.

RETRIEVABILITY:

Records are retrieved by name.

SAFEGUARDS:

Measures to prevent unauthorized disclosures are implemented as appropriate for each location. Each site implements personnel, physical, and procedural safeguards such as the following:

1. Authorized Users: Employees authorized to use the records include professional staff in the Biological Carcinogenesis Branch who have been informed of the need for maintaining confidentiality of the records.

2. Physical Safeguards: Office records are kept in closed cabinets in offices which are locked during off-duty hours.

3. Procedural Safeguards: Access to the file is strictly controlled by the system manager and his designee, and records may be removed from files only

at the request of the system manager or other authorized employee. Access to computerized records is controlled by the use of security codes known only to the authorized users.

The particular safeguards implemented at each site are developed in accordance with chapter 45–13, "Safeguarding Records Contained in Systems of Records," of the HHS General Administration Manual, supplementary chapter PHS.hf: 45–13, and part 6, "ADP Systems Security", of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361): item 7000–B–1 for exposure incident files, which does not allow records to be destroyed. Refer to the NIH Manual Chapter for specific retention instructions.

SYSTEM MANAGER AND ADDRESS:

National Cancer Institute, Division of Cancer Etiology, Program Director, Research Resources, Biological Carcinogenesis Branch, Executive Plaza North, Room 540, 6130 Executive Blvd., Bethesda, MD 20892.

NOTIFICATION PROCEDURE:

Write to the System Manager to determine if a record exists. The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

RECORD ACCESS PROCEDURE:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Write to the official specified under notification procedures above, and reasonably identify the record and specify the information being contested, the corrective action sought, and your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely or irrelevant.

The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Information is obtained from individuals and/or organizations providing specimens.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09–25–0011

SYSTEM NAME:

Clinical Research: Blood Donor Records, HHS/NIH/CC.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Department of Transfusion Medicine, National Institutes of Health, Building 10, Room 1C711, 9000 Rockville Pike, Bethesda, MD 20892.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Donors of blood and blood components to be used in the NIH Clinical Center for patient infusions.

CATEGORIES OF RECORDS IN THE SYSTEM:

Past donations, blood types, phenotypes. Laboratory results of hepatitis testing, serologic reactions on all blood samples, donations of blood or blood components.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

"Preparation of Biological Products" of the Public Health Service Act (42 U.S.C. 263).

PURPOSE OF THE SYSTEM:

(1) To provide a means for contacting blood donors for patient care and research. (2) To provide a medical history of all donors for the transfusion records of each blood unit.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure may be made to HHS contractors and their staff in order to accomplish the purposes for which the records are collected. The recipients are required to comply with the requirements of the Privacy Act with respect to such records.

2. Certain diseases and conditions, including infectious diseases, may be reported to State or Federal government as required by State or Federal law.

3. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

4. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example in defending against a claim based upon an individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, the Department may disclose such records as it deems desirable or necessary to the Department of Justice or other appropriate Federal agency to enable that agency to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

5. (a). PHS may inform the sexual and/or needle-sharing partner(s) of a subject individual who is infected with the human immunodeficiency virus (HIV) of their exposure to HIV, under the following circumstances: (1) The information has been obtained in the course of clinical activities at PHS facilities carried out by PHS personnel or contractors; (2) The PHS employee or contractor has made reasonable efforts to counsel and encourage the subject individual to provide the information to the individual's sexual or needle-sharing partner(s); (3) The PHS employee or contractor determines that the subject individual is unlikely to provide the information to the sexual or needle-sharing partner(s) or that the provision of such information cannot reasonably be verified; and (4) The notification of the partner(s) is made, whenever possible, by the subject individual's physician or by a professional counselor and shall follow standard counseling practices.

(b). PHS may disclose information to State or local public health departments, to assist in the notification of the subject individual's sexual and/or needle-sharing partner(s), or in the verification that the subject individual has notified such sexual or needle-sharing partner(s).

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored in a computer file, on donor cards, and on microfilm.

RETRIEVABILITY:

Records are retrieved by a unique control number assigned to each individual donor.

SAFEGUARDS:

Access is granted only to authorized employees in the Department of Transfusion Medicine including physicians, nurses, technologists, computer operators, and the department's administrative officer.

1. Authorized Users: Access is granted only to authorized employees of the Department of Transfusion Medicine including physicians, nurses technologists, computer operators and the secretary to the Chief.

2. Physical Safeguards: Record facilities are locked when system personnel are not present.

3. Procedural Safeguards: Access to manual files is limited to authorized users. Access to computerized records is controlled by the use of security codes known only to the authorized users.

These practices are in compliance with the standards of Chapter 45–13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45–13, and Part 6, "ADP Systems Security," of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B-361), item 3000–E–50. Refer to the NIH Manual Chapter for specific conditions on disposal.

SYSTEM MANAGER AND ADDRESS:

Chief, Department of Transfusion Medicine, National Institutes of Health, Building 10, Room 1C711, 9000 Rockville Pike, Bethesda, MD 20892.

NOTIFICATION PROCEDURE:

Write to the System Manager to determine if a record exists. The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

An individual who requests notification of or access to a medical record shall, at the time the request is made, designate in writing, a responsible representative, who may be a physician, who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

RECORD ACCESS PROCEDURE:

To obtain access to a record, contact the system manager at the address specified above. Requesters should provide the same information as is required under the notification procedures above. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Write to the official specified under notification procedures above, and reasonably identify the record and specify the information being contested, the corrective action sought, and your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Data are collected from the individual.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09–25–0012

SYSTEM NAME:

Clinical Research: Candidate Normal Volunteer Records, HHS/NIH/CC.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Social Work Department, National Institutes of Health, Building 10, Room 1C121–B, 9000 Rockville Pike, Bethesda, MD 20892.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Normally healthy individuals who volunteer to participate in NIH studies.

CATEGORIES OF RECORDS IN THE SYSTEM:

Program application, health questionnaire and record of participation.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 U.S.C. 241, 263.

PURPOSE OF THE SYSTEM:

(1) To determine suitability for participation in the normal volunteer program, (2) to document remuneration of normal volunteers, (3) to provide a record of participation to be used (a) in writing letters of recommendation/reference for the volunteer, and (b) preparing reports on the normal volunteer program.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PROGRAM OF SUCH USES:

1. Clinical research data are made available to approved or collaborating researchers, including HHS contractors and grantees.

2. Certain diseases and conditions, including infectious diseases, may be reported to appropriate representatives of State or Federal Government as required by State or Federal law.

3. Information may be used to respond to congressional inquiries for constituents concerning admission to the NIH Clinical Center.

4. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Program applications and health questionnaires are stored in file folders. Records of participation are stored on index cards.

RETRIEVABILITY:

Records are retrieved by name.

SAFEGUARDS:

Measures to prevent unauthorized disclosures are implemented as appropriate for each location and for the particular records maintained in each project. Each site implements personnel, physical, procedural safeguards such as the following:

1. Authorized Users: Access is granted only to the Normal Volunteer Program staff and to NIH physicians who have requested the recruitment of volunteers for their clinical research projects.

2. Physical Safeguards: Access to the files is strictly controlled by the files

staff. Records may be removed from the file only at the request of the system manager or other authorized employees. Record facilities are locked when system personnel are not present.

3. Procedural Safeguards: Access to the files is strictly controlled by the files staff. Records may be removed from the file only at the request of the system manager or other authorized employees.

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 3000–E–61, which allows records to be kept until superseded or for a maximum period of 3 years. Refer to the NIH Manual Chapter for specific conditions on disposal.

SYSTEM MANAGER AND ADDRESS:

Assistant Chief, Normal Volunteer Program, National Institutes of Health, Building 10, Room 1C121–B, 9000 Rockville Pike, Bethesda, MD 20892.

NOTIFICATION PROCEDURE:

Write to the System Manager to determine if a record exists. The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

An individual who requests notification of or access to a medical record shall, at the time the request is made, designate in writing, a responsible representative, who may be a physician, who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

A parent or guardian who requests notification of, or access to, a child's or incompetent person's medical record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the child or incompetent person as well as his or her own identity.

RECORD ACCESS PROCEDURE:

To obtain access to a record, contact: Assistant Chief, Normal Volunteer Program, National Institutes of Health, Building 10, Room 1C121–B, 9000 Rockville Pike, Bethesda, MD 20892 and provide the information described under Notification Procedures above. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Write to the official at the address specified under notification procedures above, and reasonably identify the record and specify the information to be contested, the corrective action sought, and the reasons for the correction, with supporting justification. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Volunteer, sponsoring contractor.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09–25–0016

SYSTEM NAME:

Clinical Research: Collaborative Perinatal Project, HHS/NIH/NINDS.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Federal Building, NIH, 7550 Wisconsin Ave., Bethesda, MD 20892.

Write to the system manager at the address below for the address of any Federal Records Center where records from this system may be stored.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Women in the perinatal study of NIH during their pregnancies, their children, husbands, fathers of children and other family members.

CATEGORIES OF RECORDS IN THE SYSTEM:

Medical histories and examinations.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 U.S.C. 241, 289a, 289c.

PURPOSE OF THE SYSTEM:

Biomedical and behavioral research by HHS scientists to discover leads to the developmental disorders of childhood by relating events of pregnancy, labor and delivery, infancy and early childhood to subsequent development of the child.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. A record may be disclosed for a research purpose, when the Department: (A) has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained; (B) has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring; (C) has required the recipient to (1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except (a) in emergency circumstances affecting the health or safety of any individual, (b) for use in another research project, under these same conditions, and with written authorization of the Department, (c) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (d) when required by law; (D) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by these provisions.

2. Certain diseases and conditions, including infectious diseases, may be reported to appropriate representatives of State or Federal Government as required by State or Federal by law.

3. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

4. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the

Justice Department has agreed to represent such employee, for example in defending against a claim based upon an individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, the Department may disclose such records as it deems desirable or necessary to the Department of Justice or other appropriate Federal agency to enable that agency to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored in file folders, on punch cards and magnetic tape, computer printouts, and on microfilm.

RETRIEVABILITY:

Records are retrieved by identifying number assigned to the mother.

SAFEGUARDS:

1. Authorized Users: Employees who maintain records in this system are instructed to grant access to HHS researchers and data processing support staff only upon receiving an approved written request from the System Manager which specifies the data to be received and the intended use of the data. A list of authorized users is maintained.

2. Physical Safeguards: Records are in an area with no other use which is locked when system is not in use.

3. Procedural Safeguards: Personnel having access are trained in Privacy requirements. Records of access to the system are maintained. Records are used in the system area or other designated work area.

This system of records will be protected according to the standards of Chapter 45–13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45–13, and Part 6, "ADP Systems Security," of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 3000–G–4, which does not allow records to be destroyed. Refer to the NIH Manual Chapter for specific retention instructions.

SYSTEM MANAGER AND ADDRESS:

Chief, Developmental Neurology Branch, National Institute of Neurological Disorders and Stroke (NINDS), Federal Building, NIH, 7550 Wisconsin Avenue, Bethesda, MD 20892.

NOTIFICATION PROCEDURE:

To determine if a record exists, write to: Chief, Administrative Services Branch, NINDS, Building 31. Room 8A49, NIH, 9000 Rockville Pike, Bethesda, MD 20892.

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

An individual who requests notification of or access to a medical/dental record shall, at the time the request is made, designate in writing, a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

A parent or guardian who requests notification of, or access to, a child's or incompetent person's medical record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the child or incompetent person as well as his or her own identity.

RECORD ACCESS PROCEDURE:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Contact the official at the address specified under notification procedures above, and reasonably identify the record and specify the information to be contested, the corrective action sought, and the reasons for the correction, with supporting justification. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Mother, child, father, biomedical examiners, hospital and clinic records, schools.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09–25–0026

SYSTEM NAME:

Clinical Research: Nervous System Studies, HHS/NIH/NINDS.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Building 36, Room 5B20, NIH, 9000 Rockville Pike, Bethesda, MD 20892.

Write to the system manager at the address below for the address of any Federal Records Center where records from this system may be stored.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Research patients in NIH-related studies having nervous system disorders.

CATEGORIES OF RECORDS IN THE SYSTEM:

Medical and demographic data.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 U.S.C. 241, 289a, 289c.

PURPOSE OF THE SYSTEM:

Clinical research by HHS scientists on patients with special diseases of the nervous system, with particular emphasis on those diseases known or thought to be caused by slow or latent viruses.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Clinical research data are made available to approved or collaborating researchers, including HHS contractors and grantees.

2. Certain diseases and conditions, including infectious diseases, may be reported to appropriate representatives of State or Federal Government as required by State or Federal law.

3. Information may be used to respond to congressional inquiries for constituents concerning admission to the NIH Clinical Center. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the

claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example in defending against a claim based upon an individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, the Department may disclose such records as it deems desirable or necessary to the Department of Justice or other appropriate Federal agency to enable that agency to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored in file folders, on magnetic tape, and on computer print-out sheets.

RETRIEVABILITY:

Records are retrieved by name, disease and attending physician name.

SAFEGUARDS:

1. Authorized Users: Employees who maintain records in this system are instructed to grant access only to scientists on the staff of the Central Nervous System Studies Laboratory and their assistants.

2. Physical Safeguards: Records are kept in a locked location.

3. Procedural Safeguards: Personnel having access to system are informed of Privacy Act requirements.

This system of records will be protected according to the standards of Chapter 45–13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45–13, and Part 6, "ADP Systems Security," of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 3000–G–3, which allows records to be kept as long as they are useful in scientific research. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER AND ADDRESS:

Chief, Central Nervous System Studies Lab., Building 36, Room 5B21, NIH, 9000 Rockville Pike, Bethesda, MD 20892.

NOTIFICATION PROCEDURE:

To determine if a record exists, contact: Chief, Administrative Services Branch, NINDS, Building 31, Room 8A49, NIH, 9000 Rockville Pike, Bethesda, MD 20892.

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

An individual who requests notification of or access to a medical/dental record shall, at the time the request is made, designate in writing, a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

RECORD ACCESS PROCEDURE:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Contact the official at the address specified under notification procedures above, and reasonably identify the record and specify the information to be contested. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Attending physicians.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09–25–0028

SYSTEM NAME:

Clinical Research: Patient Medical Histories, HHS/NIH/NINDS and HHS/NIH/NIDCD.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Building 10 & Building 31, NIH, 9000 Rockville Pike, Bethesda, MD 20892.

Write to the system manager at the address below for the address of any Federal Records Center where records from this system may be stored.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Past and present patients of the National Institute of Neurological Disorders and Stroke (NINDS) and the National Institute on Deafness and Other Communication Disorders (NIDCD), and individuals being referred for admission to the NIH Clinical Center.

CATEGORIES OF RECORDS IN THE SYSTEM:

Medical histories and diagnoses.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 U.S.C. 241, 289a, 289c.

PURPOSE OF THE SYSTEM:

Clinical research on various diseases of the nervous system and hearing, hearing loss, and communication disorders by HHS scientists and their authorized collaborators, with the specific aim of improving patient care and treatment by evaluating therapeutic procedures.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Clinical research data are made available to approved or collaborating researchers, including HHS contractors and grantees. Certain diseases and conditions, including infectious diseases, may be reported to appropriate representatives of State or Federal Government as required by State or Federal law.

2. Information may be used to respond to congressional inquiries for constituents concerning admission to the NIH Clinical Center.

3. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example in defending against a claim based upon an individual's mental or physical condition and alleged to have arisen because of activities of the Public

Health Service in connection with such individual, the Department may disclose such records as it deems desirable or necessary to the Department of Justice or other appropriate Federal agency to enable that agency to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored in file folders.

RETRIEVABILITY:

Records are retrieved by name.

SAFEGUARDS:

1. Authorized Users: Employees who maintain records in this system are instructed to grant access only to HHS researchers and their authorized collaborators.

2. Physical Safeguards: Records are kept locked in a file cabinet when not in use and in a location which is locked during non-working hours.

3. Procedural Safeguards: Records are returned to the files at the close of each working day and are used only in the system location or in a designated work area.

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 3000–G–3, which allows records to be kept as long as they are useful in scientific research. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER AND ADDRESS:

Director of Intramural Research, NINDS, Building 10, Room 5N214, NIH, 9000 Rockville Pike, Bethesda, MD 20892

and

Director of Intramural Research, NIDCD, Building 31, Room 3C06, NIH, 9000 Rockville Pike, Bethesda, MD 20892.

NOTIFICATION PROCEDURE:

To determine if a record exists, contact:

Chief, Administrative Services Branch, NINDS, Building 31, Room 8A49, NIH, 9000 Rockville Pike, Bethesda, MD 20892

or

Chief, Administrative Management Branch, NIDCD, Building 31, Room 3C21, NIH, 9000 Rockville Pike, Bethesda, MD 20892.

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine. An individual who requests notification of or access to a medical/dental record shall, at the time the request is made, designate in writing, a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

RECORD ACCESS PROCEDURE:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Contact the official at the address specified under notification procedures above, and reasonably identify the record and specify the information to be contested, the corrective action sought, and the reasons for the correction, with supporting justification. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Referring and attending physicians, hospital records.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09–25–0031

SYSTEM NAME:

Clinical Research: Serological and Virus Data in Studies Related to the Central Nervous System, HHS/NIH/NINDS.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Building 36, Room 5B21, NIH, 9000 Rockville Pike, Bethesda, MD 20892.

Write to System Manager at the address below for the address of any Federal Records Center where records from this system may be stored.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Patients with possible perinatal, acute or chronic diseases and normal volunteers in NIH-related studies pertaining to the central nervous system.

CATEGORIES OF RECORDS IN THE SYSTEM:

Clinical records, laboratory test results for viruses, pathology and identifications and characterizations of etiological agents of diseases under study, and curriculum vitae.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 U.S.C. 241, 289h.

PURPOSE OF THE SYSTEM:

Clinical research by HHS scientists and their authorized collaborators and research on blood serum, specifically to discover the role of infections (particularly those caused by a virus) in diseases of the central nervous system and also to study the role of vaccines in these diseases.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Clinical research data are made available to approved or collaborating researchers, including HHS contractors and grantees.

2. Certain diseases and conditions, including infectious diseases may be reported to appropriate representatives of State or Federal Government as required by State or Federal law.

3. Information may be used to respond to Congressional inquiries for constituents concerning admission to the NIH Clinical Center.

4. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example in defending against a claim based upon an individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, the Department may disclose such records as it deems desirable or necessary to the Department of Justice or other appropriate Federal agency to enable that agency to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored in laboratory notebooks, papers, file folders, cinematography and photography.

RETRIEVABILITY:

Records are retrieved by name and number.

SAFEGUARDS:

1. Authorized Users:

Employees who maintain records in this system are instructed to grant access only to HHS scientists and their assistants and authorized collaborators.

2. Physical Safeguards: Records are kept in cabinets which are locked at all times that system is not in use, in a location which is also locked when system is not in use.

3. Procedural Safeguards: Personnel having access to system have been trained in Privacy Act requirements. Records are used in a designated work area and the system location is attended at all times during working hours.

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 3000–G–3, which allows records to be kept as long as they are useful in scientific research. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER AND ADDRESS:

Deputy Chief, Laboratory of Central Nervous Systems Studies, Intramural Research Program, Building 36, Room 5B21, NIH, 9000 Rockville Pike, Bethesda, MD 20892.

NOTIFICATION PROCEDURE:

To determine if a record exists, contact: Chief, Administrative Services Branch, NINDS, Building 31, Room 8A49, NIH, 9000 Rockville Pike, Bethesda, MD 20892.

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

An individual who requests notification of or access to a medical/dental record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

RECORD ACCESS PROCEDURE:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Contact the official at the address specified under notification procedures above, and reasonably identify the record and specify the information to be contested, and state the corrective action sought. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Hospital records, volunteers and laboratory data.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09–25–0033

SYSTEM NAME:

International Activities: Fellowships Awarded by Foreign Organizations, HHS/NIH/FIC.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

National Institutes of Health, Building 31, Room B2C29, 9000 Rockville Pike, Bethesda, MD 20892.

Write to System Manager at the address below for the address of any Federal Records Center where records from this system may be stored.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

U.S. citizens qualified in health-related sciences submitting applications through NIH for fellowships for study abroad.

CATEGORIES OF RECORDS IN THE SYSTEM:

Applications and associated records and reports.

PURPOSE OF THE SYSTEM:

To perform scientific reviews and evaluations of applicants' suitability of referral to awarding organization in foreign countries.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 USC 2421.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. After review by the operating agency review panel the applications and all supporting documents are forwarded to the foreign organizations or agencies making awards.

2. In addition, such application may be made available to authorized employees and agents of the Federal Government for purposes of investigations, inspections and audits, and, in appropriate cases, to the Department of Justice for prosecution under civil and criminal laws.

3. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

4. Disclosure may be made to the Department of Justice, or to a court or other tribunal, when (a) HHS, or any component thereof; or (b) any HHS employee in his or her official capacity; or (c) any HHS employee in his or her individual capacity where the Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the employee; or (d) the United States or any agency thereof where HHS determines that the litigation is likely to affect HHS or any of its components, is a party to litigation or has any interest in such litigation, and HHS determines that the use of such records by the Department of Justice, court or other tribunal is relevant and necessary to the litigation and would help in the effective representation of the governmental party, provided, however that in each case, HHS determines that such disclosure is compatible with the purpose for which the records were collected.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored in file folders.

RETRIEVABILITY:

Records are retrieved by name and fellowship number.

SAFEGUARDS:

Measures to prevent unauthorized disclosures are implemented as appropriate for each location and for the particular records maintained in each project. Each site implements personnel, physical and procedural safeguards such as the following:

1. Authorized users: Employees who maintain records in this system are instructed to grant regular access only to

FIC program staff. Other one-time and special access by other employees is granted on a need-to-know basis as specifically authorized by the system manager.

2. Physical safeguards: The records are maintained in locked file cabinets, and offices are locked during off-duty hours.

3. Procedural safeguards: Access to file rooms and files is strictly controlled by files staff. Records may be removed from files only at the request of the system manager or other authorized employees.

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), items 2300–320–5, which allows records to be destroyed after a maximum period of 6 years after the close of a case. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER AND ADDRESS:

Fogarty International Center, Chief, International Research Awards Branch, National Institutes of Health, Building 31, Room B2C29, 9000 Rockville Pike, Bethesda, MD 20892.

NOTIFICATION PROCEDURE:

Requests for notification of or access to records should be addressed to the system manager, as listed above. The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

RECORD ACCESS PROCEDURE:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Contact the official under notification procedures above, and reasonably identify the record and specify the information to be contested, and state the corrective action sought, and your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely or irrelevant.

RECORD SOURCE CATEGORIES:

Applicants and persons supplying references.

SYSTEM EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09–25–0035

SYSTEM NAME:

International Activities: Health Scientist Exchange Programs, HHS/NIH/FIC.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

National Institutes of Health, Building 31, Room B2C11, 9000 Rockville Pike, Bethesda, MD 20892.

Write to system manager at the address below for the address of the Federal Records Center where records may be stored.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

U.S. citizens applying for participation in health scientist exchange programs through NIH.

CATEGORIES OF RECORDS IN THE SYSTEM:

Applications and associated records and reports, including curricula vitae and letters of reference.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 U.S.C. 2421.

PURPOSE OF THE SYSTEM:

To maintain records necessary to administer health scientist exchange programs.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

2. To qualified experts not within the definition of Department employees as prescribed in Department Regulations for opinions as a part of the application review process.

3. Information is furnished to pertinent staff of the relevant foreign ministry for acceptance purposes.

4. Applications are made available to authorized employees and agents of the Federal Government for the purpose of inspections and audits, and, in appropriate cases, to the Department of Justice for investigation under civil and criminal laws.

5. The Department of Health and Human Services (HHS) may disclose information from this system of records to the Department of Justice, or to a court or other tribunal, when (a) HHS, or any component thereof; or (b) any HHS employee in his or her official capacity; or (c) any HHS employee in his or her individual capacity where the Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the employee; or (d) the United States or any agency thereof where HHS determines that the litigation is likely to affect HHS or any of its components, is a party to litigation or has any interest in such litigation, and HHS determines that the use of such records by the Department of Justice, court or other tribunal is relevant and necessary to the litigation and would help in the effective representation of the governmental party, provided, however that in each case, HHS determines that such disclosure is compatible with the purpose for which the records were collected.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored in file folders.

RETRIEVABILITY:

Records are retrieved by name.

SAFEGUARDS:

Measures to prevent unauthorized disclosures are implemented as appropriate for each location and for the particular records maintained in each project. Each site implements personnel, physical, and procedural safeguards such as the following:

1. Authorized Users: Employees who maintain records in this system are instructed to grant regular access only to FIC program staff. Other one-time and special access by other employees is granted on a need-to-know basis as specifically authorized by the system manager.

2. Physical Safeguards: Records are kept in locked file cabinets. Offices are locked during off-duty hours.

3. Procedural Safeguards: Access to files is strictly controlled by files staff. Files may be removed only at the request of the system manager or other authorized employee.

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records"

(HHS Records Management Manual, Appendix B–361), items 2300–320–5, which allows records to be destroyed after a maximum period of 6 years after the close of a case. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER AND ADDRESS:

National Institutes of Health, Program Specialist, Health Scientist Exchange Programs, International Coordination and Liaison, Branch, FIC, Building 31, Room B2C11, 9000 Rockville Pike, Bethesda, MD 20892.

NOTIFICATION PROCEDURE:

Write to system manager to determine if a record exists. The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

RECORD ACCESS PROCEDURE:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Contact the official under notification procedures above, and reasonably identify the record and specify the information to be contested, and state the corrective action sought and the reasons for the correction, with supporting justification. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Information is obtained from applicants and individuals who supply references.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09–25–0036

SYSTEM NAME:

Extramural Awards: IMPAC (Grant/Contract/Cooperative Agreement Information), HHS/NIH/DRG.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Westwood Building, 5333 Westbard Avenue, Bethesda, MD 20892
and
Building 12, NIH Computer Center, 9000 Rockville Pike, Bethesda, MD 20892,
and
For information pertaining to the chartered advisory groups of the National Institutes of Health: Building 1, Room B1–56, 9000 Rockville Pike, Bethesda, MD 20892.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Applicant and Principal Investigators; Program Directors; NRSA Trainees and Fellows; Research Career Awardees; and Chartered Advisory Group Members.

CATEGORIES OF RECORDS IN THE SYSTEM:

Applications, awards, associated records, trainee appointments, and current and historical information pertaining to chartered advisory groups.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 U.S.C. 241c, 58 Stat. 691c and d repealed.

PURPOSE OF THE SYSTEM:

(1) To support centralized grant programs of the Public Health Service. Services are provided in the areas of grant application assignment and referral, initial review, council review, award processing and grant accounting. The data base is used to provide complete, accurate, and up-to-date reports to all levels of management.

(2) To maintain communication with former fellows and trainees who have incurred a payback obligation through the National Research Service Award Program.

(3) To maintain current and historical information pertaining to the establishment of chartered advisory groups of the National Institutes of Health and the appointment of their members.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure may be made to the National Technical Information Service (NTIS), Department of Commerce, for dissemination of scientific and fiscal information on funded awards (abstract of research projects and relevant administrative and financial data).

2. Disclosure may be made to the cognizant audit agency for auditing.

3. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

4. Disclosure may be made to qualified experts not within the definition of Department employees as prescribed in Department Regulations for opinions as a part of the application review process.

5. Disclosure may be made to a Federal agency, in response to its request, in connection with the letting of a contract, or the issuance of a license, grant or other benefit by the requesting agency, to the extent that the record is relevant and necessary to the requesting agency's decision in the matter.

6. A record may be disclosed for a research purpose, when the Department: (A) Has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained; (B) has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring; (C) has required the recipient to (1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except (a) in emergency circumstances affecting the health or safety of any individual, (b) for use in another research project, under these same conditions, and with written authorization of the Department, (c) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (d) when required by law; (D) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by these provisions.

7. The Department contemplates that it may contract with a private firm for the purpose of collating, analyzing, aggregating or otherwise refining records in this system. Relevant records will be disclosed to such a contractor. The contractor will be required to

maintain Privacy Act safeguards with respect to such records.

8. Disclosure may be made to the grantee institution in connection with performance or administration under the conditions of the award.

9. Disclosure may be made to the Department of Justice, or to a court or other tribunal, from this system of records when (a) HHS, or any component thereof; or (b) any HHS employee in his or her official capacity; or (c) any HHS employee in his or her individual capacity where the Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the employee; or (d) the United States or any agency thereof where HHS determines that the litigation is likely to affect HHS or any of its components, is a party to litigation or has any interest in such litigation, and HHS determines that the use of such records by the Department of Justice, court or other tribunal is relevant and necessary to the litigation and would help in the effective representation of the governmental party, provided, however that in each case, HHS determines that such disclosure is compatible with the purpose for which the records were collected.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored on discs and magnetic tapes.

RETRIEVABILITY:

Records are retrieved by name, application, grant or contract ID number.

SAFEGUARDS:

1. Authorized Users: Employees who maintain records in this system are instructed to grant regular access only to PHS extramural staff. Other one-time and special access by other employees is granted on a need-to-know basis as specifically authorized by the system manager.

2. Physical Safeguards: Physical access to DRG work areas is restricted to DRG employees.

3. Procedural Safeguards: Access to source data files is strictly controlled by files staff. Records may be removed from files only at the request of the system manager or other authorized employee. Access to computer files is controlled by the use of registered accounts, registered initials, keywords, etc. The computer system maintains an audit record of all attempted and successful requests for access.

These practices are in compliance with the standards of Chapter 45–13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45–13, and Part 6, "ADP Systems Security," of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 4000–A–2, which allows records to be destroyed when no longer needed for administrative purposes. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGERS AND ADDRESSES:

Chief, Information Systems Branch, Division of Research Grants, Westwood Building, 5333 Westbard Avenue, Bethesda, MD 20892

and

For information pertaining to the chartered advisory groups of the National Institutes of Health:

NIH Committee Management Officer, Building 1, Room B1–56, 9000 Rockville Pike, Bethesda, MD 20892.

NOTIFICATION PROCEDURE:

To determine if a record exists write to:

Privacy Act Coordinator, Division of Research Grants, Westwood Building, Room 449, 5333 Westbard Avenue, Bethesda, MD 20892

and

For information pertaining to the chartered advisory groups of the National Institutes of Health:

NIH Committee Management Officer, Building 1, Room B1–56, 9000 Rockville Pike, Bethesda, MD 20892.

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

RECORD ACCESS PROCEDURE:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Contact the official under notification procedures above, and reasonably identify the record and specify the information to be contested, and state the corrective action sought and the reasons for the correction, with supporting justification. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Individual, individual's educational institution and references.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09–25–0037

SYSTEM NAME:

Clinical Research: Baltimore Longitudinal Study of Aging, HHS/NIH/NIA.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

National Institutes of Health, Building 12, 9000 Rockville Pike, Bethesda, MD 20892

and

Chief, Longitudinal Studies Branch, IRP, NIA, Gerontology Research Center, 4940 Eastern Avenue, Baltimore, MD 21224.

Write to System Manager at the address below for the address of the Federal Records Center where records from this system may be stored.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Voluntary participants in the Gerontology Research Center (GRC) Longitudinal Study of Aging.

CATEGORIES OF RECORDS IN THE SYSTEM:

Medical histories, psychological and physical test results.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 USC 241, 289k–2, k–4. Health Research Extension Act of Pub. L. 99–158.

PURPOSE OF THE SYSTEM:

Research on the human aging process.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure may be made to HHS contractors, grantees and collaborating

researchers and their staff in order to accomplish the research purpose for which the records are collected. The recipients are required to maintain Privacy Act safeguards with respect to these records.

2. Certain diseases and conditions, including infectious diseases, may be reported to appropriate representatives of State or Federal Government as required by State or Federal law.

3. Information may be used to respond to congressional inquiries for constituents concerning admission to the NIH Clinical Center.

4. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example when the claim is based upon an individual's mental or physical condition and is alleged to have arisen because of activities of the Public Health Service in connection with such individual, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored in file folders and on computer files, and on microfiche.

RETRIEVABILITY:

Records are retrieved by ID number.

SAFEGUARDS:

Measures to prevent unauthorized disclosures are implemented as appropriate for each location and for the particular records maintained in each project. Each site implements personnel, physical, and procedural safeguards such as the following:

1. Authorized Users: Employees who maintain records in this system are instructed to grant regular access only to the clinical, research and support staff of the GRC. Other one-time and special access by other employees is granted on a need-to-know basis as specifically authorized by the system manager.

2. Physical Safeguards: Hard copy files are kept in locked file cabinets.

3. Procedural Safeguards: Access to manual files is strictly controlled by files staff. Files may be removed only at the request of the system manager or other authorized employee. Access to computer files is controlled through security codes known only to authorized users.

These practices are in compliance with the standards of Chapter 45–13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45–13, and Part 6, "ADP Systems Security," of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 3000–G–3, which allows records to be kept as long as they are useful in scientific research. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER AND ADDRESS:

Chief, Longitudinal Studies Branch, IRP, National Institutes of Health, Gerontology Research Center, GRC, 4940 Eastern Avenue, Baltimore, MD 21224.

NOTIFICATION PROCEDURE:

Write to System Manager to determine if a record exists. The requestor must also verify his or her identity by providing either a notarization of the request or a written certification that the requestor is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

Individuals seeking notification of or access to medical records should designate a representative (including address) who may be a physician, other health professional, or other responsible individual, who would be willing to review the record and inform the subject individual of its contents, at the representative's discretion.

RECORD ACCESS PROCEDURE:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Contact the official under notification procedures above, and reasonably identify the record and specify the information to be contested, and state the corrective action sought and the reasons for the correction, with supporting justification. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Individuals, research staff, test results.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09–25–0038

SYSTEM NAME:

Clinical Research: Patient Data, HHS/NIH/NIDDK.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

National Institutes of Health
Building 10, Room 9N222
9000 Rockville Pike
Bethesda, MD 20892

Write to System Manager at the address below for the address of the Federal Records Center where records from this system may be stored.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Patients of the National Institute of Diabetes, and Digestive and Kidney Diseases (NIDDK).

CATEGORIES OF RECORDS IN THE SYSTEM:

Patient history, demographic data, miscellaneous correspondence with patients.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 USC 241, 281a, 289c.

PURPOSE OF THE SYSTEM:

(1) Care and treatment of patients with arthritic, metabolic or digestive diseases; (2) Experimentation and investigation on the etiology, treatment and prevention of arthritic, metabolic or digestive diseases; (3) Administration of these clinical and research programs.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure may be made to HHS contractors, grantees and collaborating researchers and their staff in order to accomplish the research purpose for which the records are collected. The recipients are required to maintain Privacy Act safeguards with respect to these records.

2. Certain diseases and conditions, including infectious diseases, may be reported to appropriate representatives of State or Federal Government as required State or Federal law.

3. Information may be used to respond to congressional inquiries for constituents concerning admission to the NIH Clinical Center.

4. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example in defending against a claim based upon an individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, the Department may disclose such records as it deems desirable or necessary to the Department of Justice or other appropriate Federal agency to enable that agency to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored in file folders and on magnetic tape.

RETRIEVABILITY:

Records are retrieved by name.

SAFEGUARDS:

Measures to prevent unauthorized disclosures are implemented as appropriate for each location. Each site implements personnel, physical, and procedural safeguards such as the following:

1. Authorized Users: Employees who maintain records in this system are instructed to grant regular access only to physicians, scientists and support staff of the NIDDK whose duties require the use of such information. Other one-time and special access by other employees is granted on a need-to-know basis as specifically authorized by the system manager.

2. Physical Safeguards: Records are kept in a limited access area. Offices are locked during off-duty hours. Input data for computer files is coded to avoid individual identification.

3. Procedural Safeguards: Access to manual files is strictly controlled by files staff. Files may be removed only at the request of the system manager or other authorized employee. Access to computer files is controlled through security codes known only to authorized users. Access codes are changed frequently.

These practices are in compliance with the standards of Chapter 45–13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45–13, and Part 6, "ADP Systems Security," of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 3000–G–3, which allows records to be kept as long as they are useful in scientific research. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER AND ADDRESS:

National Institutes of Health, Chief, Clinical Investigations, NIDDK, Building 10, Room 9N222, 9000 Rockville Pike, Bethesda, MD 20892.

NOTIFICATION PROCEDURES:

To determine if a record exists write to: National Institutes of Health, Administrative Officer, Building 31, Room 9A46, 9000 Rockville Pike, Bethesda, MD 20892.

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

An individual who requests notification of or access to a medical/dental record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

RECORD ACCESS PROCEDURE:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Contact the official under notification procedures above, and reasonably identify the record and specify the information to be contested, and state the corrective action sought and the reasons for the correction, with supporting justification. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Patients.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09–25–0039

SYSTEM NAME:

Clinical Research: Diabetes Mellitus Research Study of Southwestern American Indians, HHS/NIH/NIDDK.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

National Institutes of Health, Building 12, 9000 Rockville Pike, Bethesda, MD 20892
and
Chief, Phoenix Clinical Research Section, Phoenix Area Indian Hospital, Room 541, Phoenix, Arizona 85016.

Write to System Manager at the address below for the address of the Federal Records Center where records from this system may be stored.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Southwestern American Indians and Caucasian spouses of some who were participants in the NIH Diabetes Mellitus Research Study.

CATEGORIES OF RECORDS IN THE SYSTEM:

Name, address, demographic data, patient history and control numbers.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 U.S.C. 241, 289a, 289c.

PURPOSE OF THE SYSTEM:

(1) To gain information on high prevalence of diabetes, arthritis, gall bladder and related diseases among Southwestern American Indians; (2) For statistical analysis to investigate frequency and distribution of the above disorders; (3) Data is shared with the Indian Health Service which has primary care responsibility for American Indians.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure may be made to HHS contractors, grantees and collaborating researchers and their staff in order to accomplish the research purpose for which the records are collected. The recipients are required to maintain Privacy Act safeguards with respect to these records.

2. Certain diseases and conditions, including infectious diseases, may be reported to appropriate representatives of State or Federal Government as required by State or Federal law.

3. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

4. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example in defending against a claim based upon an individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, the Department may disclose such records as it deems desirable or necessary to the Department of Justice or other appropriate Federal agency to enable that agency to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored on magnetic tapes.

RETRIEVABILITY:

Records are retrieved by name.

SAFEGUARDS:

1. Authorized Users: Employees who maintain records in this system are instructed to grant regular access only to scientists and statistical staff of the Epidemiology Branch, National Institute of Diabetes, and Digestive and Kidney Diseases (NIDDK). Other one-time and special access by other employees is granted on a need-to-know basis as specifically authorized by the system manager.

2. Physical Safeguards: Input data for computer files is coded immediately after collection to avoid individual identification. Records are kept in a limited access area equipped with a monitored burglar alarm system.

3. Procedural Safeguards: Access is strictly controlled through security codes known only to authorized users. Access codes are changed following departure of any authorized user.

The particular safeguards implemented at each site are developed in accordance with Chapter 45–13, "Safeguarding Records Contained in Systems of Records," of the HHS General Administration Manual, supplementary Chapter PHS.hf: 45–13, and part 6, ADP Systems Security, of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 3000–G–3, which allows records to be kept as long as they are useful in scientific research. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER AND ADDRESS:

National Institutes of Health, Chief, Phoenix Clinical Research Section, Phoenix Area Indian Hospital, Room 541, Phoenix, Arizona 85016.

NOTIFICATION PROCEDURE:

To determine if a record exists write to: Administrative Officer, National Institute of Diabetes, and Digestive and Kidney Diseases, NIH, Building 31, Room 9A46, 9000 Rockville Pike, Bethesda, MD 20892.

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

An individual who requests notification of or access to a medical/dental record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

RECORD ACCESS PROCEDURE:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Contact the official under notification procedures above, and reasonably identify the record and specify the information to be contested, and state the corrective action sought and the reasons for the correction, with supporting justification. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Patients.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09–25–0040

SYSTEM NAME:

Clinical Research: Southwestern American Indian Patient Data, HHS/NIH/NIDDK.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Phoenix Area Indian Hospital, Room 541, Phoenix, Arizona 85016.

Write to system manager at the address below for the address of the Federal Records Center where records from this system may be stored.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Patients of the National Institute of Diabetes, and Digestive and Kidney Diseases (NIDDK) being treated at the Phoenix Area Indian Hospital.

CATEGORIES OF RECORDS IN THE SYSTEM:

Medical history, treatment schedules, diagnostic records.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 USC 241, 289a, 289c.

PURPOSE OF THE SYSTEM:

(1) Used by clinicians and support staff of the Phoenix Clinical Research Section for treatment of NIDDK patients, and for research related to such treatment.

(2) Records are forwarded to the Indian Health Service which maintains records after patient discharge in case follow-up or later treatment is necessary.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure may be made to HHS contractors, grantees and collaborating researchers and their staff in order to accomplish the research purpose for which the records are collected. The recipients are required to maintain Privacy Act safeguards with respect to these records.

2. Certain diseases and conditions, including infectious diseases, may be reported to appropriate representatives of State or Federal Government as required by State or Federal law.

3. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

4. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example in defending against a claim based upon an individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, the Department may disclose such records as it deems desirable or necessary to the Department of Justice or other appropriate Federal agency to enable that agency to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored in file folders.

RETRIEVABILITY:

Records are retrieved by name and patient number.

SAFEGUARDS:

1. Authorized Users: Personnel screen users to prevent unauthorized access.

2. Physical Safeguards: Records are maintained in secured areas and containers.

3. Procedural Safeguards: Charge-out records are maintained on records charged out from the files.

RETENTION AND DISPOSAL:

Records are retained and destroyed according to the same standards that apply to other medical records of the Indian Health Service.

SYSTEM MANAGER AND ADDRESS:

Chief, Phoenix Clinical Research Section, Phoenix Area Indian Hospital, Room 541, 4212 North 16th Street, Phoenix, Arizona 85016.

NOTIFICATION PROCEDURE:

To determine if a record exists write to: National Institutes of Health, Administrative Officer, NIDDK, Building 31, Room 9A46, 9000 Rockville Pike, Bethesda, MD 20892.

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

An individual who requests notification of or access to a medical/dental record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

A parent or guardian who requests notification of, or access to, a child's or incompetent person's medical record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the child or incompetent person as well as his or her own identity.

RECORD ACCESS PROCEDURES:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Contact the official under notification procedures above, and reasonably identify the record and specify the information to be contested, and state the corrective action sought and the reasons for the correction, with supporting justification. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Clinicians of the Phoenix Clinical Research Section.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09-25-0042

SYSTEM NAME:

Clinical Research: National Institute of Dental Research Patient Records, HHS/NIH/NIDR.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

National Institutes of Health, Building 10, Room 1B01, 9000 Rockville Pike, Bethesda, MD 20892.

Write to system manager at the address below for the address of the Federal Records Center where records from this system may be stored.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Patients and other participants in current and past research projects of the National Institute of Dental Research (NIDR).

CATEGORIES OF RECORDS IN THE SYSTEM:

Medical and dental histories, dental pathologies and therapies.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Sections 301, 401, 405 and 453 of the Public Health Service Act (42 U.S.C. 241, 281, 284, 285h). These sections establish the National Institute of Dental Research and authorize the conduct and support of dental and oral research and related activities.

PURPOSE OF THE SYSTEM:

(1) To record the diagnosis and treatment of patients with diseases of the mouth, tongue, teeth and surrounding tissues; (2) To record the normal condition of the mouth, tongue, teeth and surrounding tissues of individuals referred to the dental clinic; (3) To provide clinical data for research into the etiology, treatment and prevention of oral diseases; (4) For review and planning of the NIDR clinical program.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure may be made to HHS contractors, grantees and collaborating researchers and their staff in order to accomplish the clinical and research purposes for which the records are collected. The recipients are required to maintain Privacy Act safeguards with respect to these records.

2. Certain diseases and conditions, including infectious diseases, may be reported to appropriate representatives of State or Federal Government as required by State or Federal law.

3. Information may be used to respond to congressional inquiries for constituents concerning admission to the NIH Clinical Center.

4. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example, when a claim is based upon an individual's mental or physical condition and is alleged to have arisen because of activities of the Public Health Service in connection with such individual, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored in file folders.

RETRIEVABILITY:

Records are retrieved by name and hospital ID number.

SAFEGUARDS:

Measures to prevent unauthorized disclosures are implemented as appropriate for each location and for the particular records maintained in each project. Each site implements personnel, physical, and procedural safeguards such as the following:

1. Authorized Users: Employees who maintain records in this system are instructed to grant regular access only to dentists, physicians, dental hygienists, dental assistants and other health care personnel involved in the care and treatment of patients in the NIDR dental clinic, and to referring professionals. Other one-time and special access by other employees is granted on a need-to-know basis as specifically authorized by the system manager.

2. Physical Safeguards: Records are stored in a cabinet which is locked at all times when not in use.

3. Procedural Safeguards: Access is controlled by clerical staff of the Dental Clinic during clinic hours, and by the Officer of the Day when the clinic is closed.

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 3000–G–3, which allows records to be kept as long as they are useful in scientific research. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER AND ADDRESS:

National Institutes of Health, Chief, Clinical Investigations and Patient Care Branch, NIDR, Building 10, Room 1N–113, 9000 Rockville Pike, Bethesda, MD 20892.

NOTIFICATION PROCEDURE:

To determine if a record exists contact: NIDR Privacy Act Coordinator, Building 31, Room 2C–35, 9000 Rockville Pike, Bethesda, MD 20892.

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine. An individual who requests notification of or access to a medical/dental record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

A parent or guardian who requests notification of, or access to, a child's or incompetent person's medical record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the child or incompetent person as well as his or her own identity.

RECORD ACCESS PROCEDURE:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Contact the official under notification procedures above, and reasonably identify the record and specify the information to be contested, and state the corrective action sought and the reasons for the correction, with supporting justification. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Individual, parents or guardians.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09–25–0044

SYSTEM NAME:

Clinical Research: Sensory Testing Research Program, HHS/NIH/NIDR.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

National Institutes of Health, Building 10, Room 1–N–114, 9000 Rockville Pike, Bethesda, MD 20892.

Write to System Manager at the address below for the address of the Federal Records Center where records from this system may be stored.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Infants, children and adults participating in the Sensory Testing Research Program of the National Institute of Dental Research (NIDR).

CATEGORIES OF RECORDS IN THE SYSTEM:

Test results, extracts from medical records.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Sections 301, 401, 405 and 453 of the Public Health Service Act (42 U.S.C. 241, 281, 284, 285h). These sections establish the National Institute of Dental Research and authorize the conduct and support of dental and oral research and related activities.

PURPOSE OF THE SYSTEM:

(1) To record the medical/dental histories of individuals participating in the Sensory Testing Research Program; (2) To record the results of chemosensory tests of individuals participating in the Sensory Testing Research Program; (3) For research on sensitivity to oral nasal stimulation; (4) For review and planning of the Clinical Investigations and Patient Care Branch program.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure may be made to HHS contractors, grantees, referring health professionals and collaborating researchers and their staff in order to accomplish the clinical and research purposes for which the records are collected. The recipients are required to maintain Privacy Act safeguards with respect to these records.

2. Certain diseases and conditions, including infectious diseases, may be reported to appropriate representatives of State or Federal Government as required by State or Federal law.

3. Information may be used to respond to congressional inquiries for constituents concerning admission to the NIH Clinical Center.

4. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example, when a claim is based upon an individual's mental or physical condition and is alleged to have arisen because of activities of the Public Health Service in connection with such individual, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored in file folders, data books and in a mini-computer maintained by the NIDR Scientific Systems Section.

RETRIEVABILITY:

Records are retrieved by name, date of observation and age of subject.

SAFEGUARDS:

Measures to prevent unauthorized disclosures are implemented as appropriate for each location and for the particular records maintained in each project. Each site implements personnel, physical and procedural safeguards such as the following:

1. Authorized Users: Employees who maintain records in this system are instructed to grant regular access only to Clinical Investigations Section staff, to scientist colleagues by invitation of the principal investigator and to referring professionals. Other one time and special access by other employees is granted on a need to know basis as specifically authorized by the System Manager.

2. Physical Safeguards: Records are stored in rooms which are locked at all times when not in use. Computer terminals are in secured areas. Access to computer file is controlled by software protection codes associate with each site.

3. Procedural Safeguards: Access is controlled by Clinical Investigation Section staff.

These safeguards are in compliance with the standards of Chapter 45–13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45–13, and Part 6, "ADP Systems Security," of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 3000–G–3, which allows records to be kept as long as they are useful in scientific research. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER AND ADDRESS:

Research Psychologist, Clinical Investigations, NIDR, Building 10, Room 1N114, 9000 Rockville Pike, Bethesda, MD 20892.

NOTIFICATION PROCEDURE:

To determine if a record exists contact: NIDR Privacy Act Coordinator, 9000 Rockville Pike, Building 31, Room 2C–35, Bethesda, MD 20892.

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine. An individual who requests notification of or access to a medical/dental record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

A parent or guardian who requests notification of, or access to, a child's or incompetent person's medical record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the child or incompetent person as well as his or her own identity.

RECORD ACCESS PROCEDURE:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Contact the official under notification procedures above, and reasonably identify the record and specify the information to be contested, and state the corrective action sought and the reasons for the correction, with supporting justification. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Subject individual, cooperating clinician or health agency, family members.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09–25–0046

SYSTEM NAME:

Clinical Research: Catalog of Clinical Specimens from Patients, Volunteers and Laboratory Personnel, HHS/NIH/NIAID.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Building 7, Rooms 106 and 202, NIH, 9000 Rockville Pike, Bethesda, MD 20892.

Write to System Manager at the address below for the address of the Federal Records Center where records from this system may be stored.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Patients, volunteers, laboratory personnel in the National Institute of Allergy and Infectious Diseases (NIAID).

CATEGORIES OF RECORDS IN THE SYSTEM:

Clinical specimens, attendant data and laboratory results.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 U.S.C. 241, 289a, 289c.

PURPOSE OF THE SYSTEM:

For diagnostic and epidemiologic studies of viral respiratory diseases and hepatitis, conducted by NIAID staff.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure may be made to HHS contractors, grantees and collaborating researchers and their staff in order to accomplish the research purpose for which the records are collected. The recipients are required to maintain Privacy Act safeguards with respect to these records.

2. Certain diseases and conditions, including infectious diseases, may be reported to appropriate representatives of State or Federal Government as required by State or Federal law.

3. Information may be used to respond to congressional inquiries for constituents concerning admission to the NIH Clinical Center.

4. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example, when a claim is based upon an individual's mental or physical condition and is alleged to have arisen because of activities of the Public Health Service in connection with such individual, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored in data books.

RETRIEVABILITY:

Records are retrieved by name, patient or study number.

SAFEGUARDS:

1. Authorized Users: Employees who maintain records in this system are instructed to grant regular access only to HHS scientists conducting research, and staff whose duties require the use of such information. Other one time and special access by other employees is granted on a need to know basis as specifically authorized by the System Manager.

2. Physical Safeguards: Data books are kept in locked rooms. Offices are locked during off-duty hours.

3. Procedural Safeguards: Access to files is strictly controlled by files staff. Records may be removed from files only at the request of the System Manager or other authorized employee.

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 3000–G–3, which allows records to be kept as long as they are useful in scientific research. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER AND ADDRESS:

Chief, Respiratory Viruses Section, LID, NIAID, Building 7, Room 106, NIH, 9000 Rockville Pike, Bethesda, MD 20892; and

Chief, Hepatitis Virus Section, NIAID, Building 7, Room 202, NIH, 9000 Rockville Pike, Bethesda, MD 20892.

NOTIFICATION PROCEDURE:

To determine if a record exists, write to: Privacy Act Coordinator, NIAID, Control Data Building, Room 4C–01, 6003 Executive Blvd., Rockville, MD 20892.

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

A parent or guardian who requests notification of, or access to, a child's or incompetent person's medical record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the child or incompetent person as well as his or her own identity.

RECORD ACCESS PROCEDURE:

Same as notification procedure above. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Write to the official specified under notification procedures above, and reasonably identify the record and specify the information being contested, the corrective action sought, and your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely or irrelevant. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Information contained in these records is obtained directly from individual participants and from medical records, field study records, and clinical research observations.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09-25-0048

SYSTEM NAME:

Clinical Research: Serology-Epidemiology Parasite Research, HHS/NIH/NIAID.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Rocky Mountain Laboratories, NIH, Hamilton, MT 59840.

Write to System Manager at the address below for the address of the Federal Records Center where records from this system may be stored.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Blood or parasite donors participating in serology-epidemiology parasite research of the National Institute of Allergy and Infectious Diseases (NIAID).

CATEGORIES OF RECORDS IN THE SYSTEM:

Results of blood tests and possible case histories.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 U.S.C. 241, 289a, 289c.

PURPOSE OF THE SYSTEM:

For serologic and epidemiologic studies on parasitic and rickettsial diseases (Rocky Mountain spotted fever, in particular) conducted by NIAID staff.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure may be made to HHS contractors, grantees and collaborating researchers and their staff in order to accomplish the research purpose for which the records are collected. The recipients are required to maintain Privacy Act safeguards with respect to these records.

2. Certain diseases and conditions, including infectious diseases, may be reported to appropriate representatives of State or Federal Government as required by State or Federal law.

3. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

4. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example, when a claim is based upon an individual's mental or physical condition and is alleged to have arisen because of activities of the Public Health Service in connection with such individual, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored in file folders.

RETRIEVABILITY:

Records are retrieved by name.

SAFEGUARDS:

1. Authorized Users: Employees who maintain records in this system are instructed to grant regular access only to HHS scientists conducting research, and staff whose duties require the use of such information. Other one-time and special access by other employees is granted on a need-to-know basis as specifically authorized by the system manager.

2. Physical Safeguards: Offices are locked during off-duty hours.

3. Procedural Safeguards: Access to files is strictly controlled by files staff. Records may be removed from files only at the request of the system manager or other authorized employee.

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B-361), item 3000-G-3, which allows records to be kept as long as they are useful in scientific research. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER AND ADDRESS:

Chief, Rocky Mountain Operations Branch, Rocky Mountain Laboratories, NIH, Hamilton, MT 59840.

NOTIFICATION PROCEDURE:

To determine if a record exists write to Privacy Act Coordinator, NIAID, Control Data Building, Room 4C-01, 6003 Executive Blvd., Bethesda, MD 20892.

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

Individuals seeking notification of or access to medical records should designate a representative (including address) who may be a physician, other health professional, or other responsible individual, who would be willing to review the record and inform the subject individual of its contents, at the representative's discretion.

RECORD ACCESS PROCEDURE:

Same as notification procedure above. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Write to the official specified under notification procedures above, and reasonably identify the record and specify the information being contested, the corrective action sought, and your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely or irrelevant. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Personal physician of donor and state health departments.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09-25-0053

SYSTEM NAME:

Clinical Research: Vision Studies, HHS/NIH/NEI.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

National Institutes of Health, Building 10, Room 10N202, CC, 9000 Rockville Pike, Bethesda, MD 20892.

Write to System Manager at the address below for the address of the Federal Records Center where records from this system may be stored.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Patients and subjects in the National Eye Institute research studies.

CATEGORIES OF RECORDS IN THE SYSTEM:

Medical history as relevant to vision research.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 U.S.C. 241, 289i, 289k.

PURPOSE OF THE SYSTEM:

(1) To gather photographic evidence of various stages or progressions of certain visual disorders; (2) To record certain diagnostic test results (such as color vision testing) in the compilation of empirical data to support research evaluations.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure may be made to HHS contractors, grantees and collaborating researchers and their staff in order to accomplish the research purpose for which the records are collected. The recipients are required to maintain Privacy Act safeguards with respect to these records.

2. Information may be used to respond to Congressional inquiries for constituents concerning admission to the NIH Clinical Center.

3. Certain diseases and condition, including infectious diseases, may be reported to appropriate representatives of State or Federal Government as required by State or Federal law.

4. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example in defending against a claim based upon an individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, the Department may disclose such records as it deems desirable or necessary to the Department of Justice or other appropriate Federal agency to enable that agency to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored in file cabinets.

RETRIEVABILITY:

Records are retrieved by name and cross referenced by anatomical entity.

SAFEGUARDS:

1. Authorized Users: Employees who maintain records in this system are instructed to grant regular access only to HHS scientists conducting research and physicians treating the patient whose records are involved. Other one time and special access by other employees is granted on a need to know basis as specifically authorized by the system manager.

2. Physical Safeguards: File cabinets are in locked rooms and access to files is strictly controlled.

3. Procedural Safeguards: Specifically, records may be removed from files only at the request of the System Manager or authorized employees.

These practices are in compliance with the standards of Chapter 45–13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45–13, and Part 6, "ADP Systems Security," of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 3000–G–3, which allows records to be kept as long as they are useful in scientific research. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER AND ADDRESS:

National Institutes of Health, Clinical Director, NEI, Building 10, Room 10N–202, 9000 Rockville Pike, Bethesda, MD 20892.

NOTIFICATION PROCEDURE:

To determine if a record exists, contact: Executive Officer, NEI, Building 31, Room 6A07, NIH, 9000 Rockville Pike, Bethesda, MD 20892.

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

An individual who requests notification of or access to a medical/dental record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

RECORD ACCESS PROCEDURE:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Contact the official under notification procedures above, and reasonably identify the record and specify the information to be contested, and state the corrective action sought. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Medical examinations conducted by and under the direction of the research investigators.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09–25–0054

SYSTEM NAME:

Administration: Property Accounting, HHS/NIH/ORS.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

National Institutes of Health, Building 13, Room 2E43, 9000 Rockville Pike, Bethesda, MD 20892; and

National Institutes of Health, Computer Center, Building 12, 9000 Rockville Pike, Bethesda, MD 20892; and

National Institutes of Health, Building 31, Room B1C06, 9000 Rockville Pike, Bethesda, MD 20892; and

National Institute of Environmental Health Sciences, Office of Facilities Engineering, 102–01, P.O. Box 12233, Research Triangle Park, N.C. 27709.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Employees of the National Institutes of Health who are issued tools or card keys.

CATEGORIES OF RECORDS IN THE SYSTEM:

Property management.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301; 5 U.S.C. 5901; 5 U.S.C. 7903; 40 U.S.C. 318a; 42 U.S.C. 241.

PURPOSE OF THE SYSTEM:

Used for tool and card keys issuance and control.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

2. In the event that a system of records maintained by this agency to carry out its functions indicates a violation or potential violation of law, whether civil, criminal or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule or order issued pursuant thereto, the relevant records in the system of records may be referred, as a routine use, to the appropriate agency, whether federal, or foreign, charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute, or rule, regulation or order issued pursuant thereto.

3. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored in file folders, and on magnetic media.

RETRIEVABILITY:

Records are retrieved by name.

SAFEGUARDS:

1. Authorized Users: Employees who maintain records in this system are instructed to grant regular access only to officials whose duties require use of the information. Other one time and special access by other employees is granted on a need to know basis as specifically authorized by the system manager.

2. Physical Safeguards: Textual records are stored in offices which are locked when not in use.

3. Procedural Safeguards: Computer files are password protected.

This system of records will be protected according to the standards of Chapter 45–13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45–13, and Part 6, "ADP Systems Security," of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 1300–C–14, which allows records to be destroyed after all listed credentials are accounted for or 3 months after the return of credentials to the issuing office. Refer to the NIH Manual Chapter for specific instructions.

SYSTEM MANAGER AND ADDRESS:

For tools: National Institutes of Health, Administrative Officer, DES, Building 13, Room 13/2E43, 9000 Rockville Pike, Bethesda, MD 20892.

For card keys: National Institutes of Health, Chief, Crime Prevention Section, Security Branch, DS, ORS, Building 31, Room B3B16, 9000 Rockville Pike, Bethesda, MD 20205.

National Institute of Environmental Health Sciences, Chief, Office of Facilities Engineering, 102–01, P.O. Box 12233, Research Triangle Park, NC 27709.

NOTIFICATION PROCEDURE:

Write to the System Manager to determine if a record exists. The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

RECORD ACCESS PROCEDURE:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Write to the official specified under notification procedures above, and reasonably identify the record and specify the information being contested, the corrective action sought, and your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely or irrelevant. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Data is obtained from the individual.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09–25–0060

SYSTEM NAME:

Clinical Research: Division of Cancer Treatment Clinical Investigations, HHS/NIH/NCI.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

National Institutes of Health, 8601 Old Georgetown Road, Bethesda, MD 20892; and

Frederick Cancer Research and Development Center, Building 426, Frederick, MD 21701; and

National Cancer Institute, Biological Response Modifiers Program (BRMP), 501 W. 7th Street, Suite #3, Frederick, MD 21701; and

National Cancer Institute, Navy Hospital, Building 8, Room 3146, Bethesda, MD 21814; and

National Cancer Institute, Division of Cancer Treatment, Cancer Therapy

Evaluation Program, Executive Plaza North, Room 707, Bethesda, MD 20892

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

All patients who have been hospitalized or seen in outpatient clinics on treatment research protocols in the National Cancer Institute.

CATEGORIES OF RECORDS IN THE SYSTEM:

Medical records.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 USC 241, 281, 282.

PURPOSE(S) OF THE SYSTEM:

(1) Patient care and treatment. (2) Clinical and epidemiological research.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure may be made to HHS contractors, grantees and collaborating researchers and their staff in order to accomplish the research purpose for which the records are collected. The recipients are required to maintain Privacy Act safeguards with respect to these records.

2. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

3. Disclosure may be made to a contractor when the Department contemplates that it will contract with a private firm for the purpose of collating, analyzing, aggregating or otherwise refining records in this system. Relevant records will be disclosed to such a contractor. The contractor shall be required to maintain Privacy Act safeguards with respect to such records.

4. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example in defending against a claim based upon an individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, the Department may disclose such records as it deems desirable or necessary to the Department of Justice or other appropriate Federal agency to enable that agency to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored on magnetic tapes, microcomputer disks, index cards, microfiche, and manual paper records.

RETRIEVABILITY:

Records are retrieved by patient name or number.

SAFEGUARDS:

Measures to prevent unauthorized disclosures are implemented as appropriate for each location and for the particular records maintained in each project. Each site implements personnel, physical, and procedural safeguards such as the following:

1. Authorized Users: Employees who maintain records in this system are instructed to grant regular access only to physicians, scientists and support staff of the National Cancer Institute, or its contractors, whose duties require the use of such information. Other one-time and special access by other employees is granted on a need-to-know basis as specifically authorized by the system manager.

2. Physical Safeguards: Records are kept in a limited access area. Offices are locked during off-duty hours. Input data for computer files is coded to avoid individual identification.

3. Procedural Safeguards: Access to manual files is strictly controlled by files staff. Files may be accessed only at the request of the system manager or other authorized employee. Access to computer files is controlled through security codes known only to authorized users. Access codes are changed frequently.

These practices are in compliance with the standards of Chapter 45–13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45–13, and Part 6, "ADP Systems Security," of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 3000–G–3, which allows records to be kept as long as they are useful in scientific research. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER AND ADDRESS:

Head, Biostatistics and Data Management Section, National Institutes of Health, 8601 Old Georgetown Road, Bethesda, MD 20892; and

Chief, Clinical Research Branch, Biological Response Modifiers Program, Frederick Cancer Research and Development Center, 501 W. 7th Street, Suite #3, Frederick, MD 21701; and

Navy Hospital, Deputy Branch Chief, NCI—Naval Medical Oncology Branch, Building 8, Room 5101, Bethesda, MD 20814; and

Head, Drug Management and Authorization Section, Cancer Therapy Evaluation Program, Division of Cancer Treatment, National Cancer Institute, Executive Plaza North, Room 707, Bethesda, MD 20892.

NOTIFICATION PROCEDURE:

Write to system manager for the appropriate location to determine if a record exists. The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

An individual who requests notification of or access to a medical/dental record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

A parent or guardian who requests notification of, or access to, a child's or incompetent person's medical record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the child or incompetent person as well as his or her own identity.

RECORD ACCESS PROCEDURE:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of

accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Contact the official under notification procedures above, and reasonably identify the record and specify the information to be contested, and state the corrective action sought. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Hospital medical records, referring physician, referring hospitals, clinical laboratories, patient contact, and Central Tumor Registries.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09-25-0069

SYSTEM NAME:

NIH Clinical Center Admissions of the National Cancer Institute, HHS/NIH/NCI.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

National Institutes of Health, Executive Plaza North, Rooms 400 and 439, 6130 Executive Blvd., Bethesda, MD 20892; and

National Institutes of Health, Division of Computer Research and Technology, Building 12A, 9000 Rockville Pike, Bethesda, MD 20892; and

WESTAT, Inc., STSC Building, Suite 402, 2115 E. Jefferson Street, Rockville, MD 20852; and

Survey Research Associates, Inc., 6115 Falls Road, Baltimore, MD 21209

Write to System Manager at the address below for the address of the Federal Records Center where records from this system may be stored.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Current and former cancer patients and their family members admitted to the NIH Clinical Center or the National Cancer Institute (NCI).

CATEGORIES OF RECORDS IN THE SYSTEM:

Medical histories, reports and correspondence.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 U.S.C. 285a

PURPOSE OF THE SYSTEM:

National Cancer Institute physicians and supporting staff are involved in research on the cause and diagnosis of disease and the treatment of patients, requiring the maintenance of working files to chart progress, responses to treatment, etc.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure may be made to HHS contractors, grantees and collaborating researchers and their staff in order to accomplish the research purpose for which the records are collected. The recipients are required to maintain Privacy Act safeguards with respect to these records.

2. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

3. Disclosure may be made to a contractor when the Department contemplates that it will contract with a private firm for the purpose of collating, analyzing, aggregating or otherwise refining records in this system. Relevant records will be disclosed to such a contractor. The contractor shall be required to maintain Privacy Act safeguards with respect to such records.

4. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example in defending against a claim based upon an individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, the Department may disclose such records as it deems desirable or necessary to the Department of Justice or other appropriate Federal agency to enable that agency to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

5. (a). PHS may inform the sexual and/or needle-sharing partner(s) of a subject individual who is infected with the human immunodeficiency virus (HIV) of their exposure to HIV, under the following circumstances: (1) The information has been obtained in the course of clinical activities at PHS facilities carried out by PHS personnel or contractors; (2) The PHS employee or contractor has made reasonable efforts to counsel and encourage the subject individual to provide the information to the individual's sexual or needle-sharing partner(s); (3) The PHS employee or contractor determines that the subject individual is unlikely to provide the information to the sexual or needle-sharing partner(s) or that the provision of such information cannot reasonably be verified; and (4) The notification of the partner(s) is made, whenever possible, by the subject individual's physician or by a professional counselor and shall follow standard counseling practices.

(b). PHS may disclose information to State or local public health departments, to assist in the notification of the subject individual's sexual and/or needle-sharing partner(s), or in the verification that the subject individual has notified such sexual or needle-sharing partner(s).

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored in file folders and on computer files.

RETRIEVABILITY:

Records are retrieved by identification number.

SAFEGUARDS:

Measures to prevent unauthorized disclosures are implemented as appropriate for each location and for the particular records maintained in each project. Each site implements personnel, physical and procedural safeguards such as the following:

1. Authorized Users: Employees who maintain records in this system are instructed to grant regular access only to physicians, scientists and support staff of the National Cancer Institute and the Clinical Center whose duties require the use of such information. Other one-time and special access by other employees is granted on a need-to-know basis as specifically authorized by the system manager.

2. Physical Safeguards: Records are kept in limited access areas. Offices are locked during off-duty hours. Input data for computer files is coded to avoid individual identification.

3. Procedural Safeguards: Access to manual files is strictly controlled by files staff. Files may be accessed only at the request of the system manager or other authorized employee. Access to computer files is controlled through security codes known only to authorized users. Access codes are changed frequently.

These practices are in compliance with the standards of Chapter 45–13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45–13, and Part 6, "ADP Systems Security," of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 3000–G–3, which allows records to be kept as long as they are useful in scientific research. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER AND ADDRESS:

National Institutes of Health, National Cancer Institute, Division of Cancer Etiology, Epidemiology and Biostatistics Program, Chief, Family Studies Section, Environmental Epidemiology Branch, Executive Plaza North, Suite 439, Bethesda, MD 20892; and

Acting Chief, Clinical Genetics Section, Clinical Epidemiology Branch, Executive Plaza North, Suite 400, Bethesda, MD 20892.

NOTIFICATION PROCEDURE:

, Write to system manager to determine if a record exists. The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

An individual who requests notification of or access to a medical/dental record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

A parent or guardian who requests notification of, or access to, a child's or incompetent person's medical record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the child or incompetent person as well as his or her own identity.

RECORD ACCESS PROCEDURE:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought.

Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Contact the official under notification procedures above, and reasonably identify the record and specify the information to be contested, and state the corrective action sought. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Patients' personal physicians, NIH staff treating the patients or performing tests, requested outside records, and patients themselves.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09–25–0077

SYSTEM NAME:

Biological Carcinogenesis Branch Human Specimen Program, HHS/NIH/NCI.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

National Institutes of Health, Executive Plaza North, Rm. 540, 6130 Executive Blvd., Bethesda, MD 20892 and at private organizations under contract. Write to the system manager for a list of current locations.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Cancer and other patients, and normal donors of biopsy and tumor specimens, who are seen at clinically-oriented organizations under contract to the National Cancer Institute. Both adults and children are covered.

CATEGORIES OF RECORDS IN THE SYSTEM:

Medical history and diagnostic information about the donor, information on the type of specimen, location of repository (if specimen is stored before use), and distribution record.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 USC 241, 281, 282: "Research and Investigation," "National Cancer Institute," and "Cancer Research and Other Activities."

PURPOSE(S) OF THE SYSTEM:

(1) For cancer research, using by-products of cancer treatment, such as biopsy and tumor specimens that would normally be discarded, to allow interpretation of experimental results; (2) To project future research needs; (3) To monitor and evaluate the NCI distribution system.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. The Department contemplates that it may contract with a private firm for storage and preservation of specimens. Records necessary for identification, retrieval and research use will be disclosed to such a contractor. The contractor will be required to comply with the requirements of the Privacy Act with respect to such records.

2. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

3. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

File folder, magnetic tape, and discs.

RETRIEVABILITY:

Retrieved by name of donor and cross-referenced by identifying number, procurement source, and various epidemiological characteristics.

SAFEGUARDS:

Measures to prevent unauthorized disclosures are implemented as appropriate for each location and for the particular records maintained in each project. Each site implements personnel,

physical and procedural safeguards such as the following:

1. Authorized Users: Employees who maintain records in this system are instructed to grant regular access only to physicians, scientists and support staff of the National Cancer Institute, or its contractors, whose duties require the use of such information. Other one-time and special access by other employees is granted on a need-to-know basis as specifically authorized by the system manager.

2. Physical Safeguards: Records, computers and computer terminals are kept in limited access areas. Offices are locked during off-duty hours. Input data for computer files is coded to avoid individual identification.

3. Procedural Safeguards: Access to manual files is strictly controlled by files staff. Files may be accessed only at the request of the system manager or other authorized employee. Access to computer files is controlled through security codes known only to authorized users.

Contractor compliance is assured through inclusion of Privacy Act requirements in contract clauses, and through monitoring by contract and project officers. Contractors who maintain records in this system are instructed to make no disclosure of the records except as authorized by the system manager.

These practices are in compliance with the standards of Chapter 45–13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45–13, and Part 6, "ADP Systems Security," of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 3000–G–3, which allows records to be kept as long as they are useful in scientific research. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER AND ADDRESS:

Program Director, Research Resources, Biological Carcinogenesis Branch, Division of Cancer Etiology, NCI, National Institutes of Health, Executive Plaza North, Room 540, 6130 Executive Blvd., Bethesda, MD 20892.

NOTIFICATION PROCEDURE:

Write to System Manager to determine if a record exists. The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

An individual who requests notification of or access to a medical/dental record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

A parent or guardian who requests notification of, or access to, a child's or incompetent person's medical record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the child or incompetent person as well as his or her own identity.

RECORD ACCESS PROCEDURE:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Contact the official under notification procedures above, and reasonably identify the record and specify the information to be contested, and state your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely or irrelevant. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Specimen Report Form filled out by the organization providing specimens.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09–25–0087

SYSTEM NAME:

Administration: Employees and Consultants, HHS/NIH/NIAID.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

National Institutes of Health, Building 31, Room 7A32, 9000 Rockville Pike, Bethesda, MD 20892.

Write to System Manager at the address below for the address of the Federal Records Center where records from this system may be stored.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Current and former key professional employees of the Institute and consultants.

CATEGORIES OF RECORDS IN THE SYSTEM:

Press releases, curriculum vitae, nominations for awards and photographs.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 U.S.C. 241(d) 289a.

PURPOSE OF THE SYSTEM:

For background records to provide public announcements on National Institute of Allergy and Infectious Diseases (NIAID) Council members, advisors and guest lecturers.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Stored in file folders.

RETRIEVABILITY:

Retrieved by name.

SAFEGUARDS:

Measures to prevent unauthorized disclosures are implemented as appropriate for each location and for the particular records maintained in each project. Each site implements personnel, physical, and procedural safeguards such as the following:

1. Authorized Users: Employees who maintain records in this system are instructed to grant regular access only to staff whose duties require the use of such information. Authorized users are located in the Office of the Director, NIAID. Other one time and special access by other employees is granted on a need-to-know basis as specifically authorized by the system manager.

2. Physical Safeguards: Records in this system are stored in file folders which are kept in locked cabinets. The room is locked during off-duty hours.

3. Procedural Safeguards: Access to files is strictly controlled by files staff. Records may be removed from files only at the request of the system manager or other authorized employee.

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 1100–G. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER AND ADDRESS:

Director, Office of Communications, National Institutes of Health, Building 31, Room 7A32, 9000 Rockville Pike, Bethesda, MD 20892.

NOTIFICATION PROCEDURE:

To determine if a record exists, write to: National Institutes of Health, Privacy Act Coordinator, NIAID, Control Data Bldg., Room 4C–01, 6003 Executive Blvd., Rockville, MD 20892.

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

RECORD ACCESS PROCEDURE:

Same as record notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Contact the System Manager at the address above, and reasonably identify the record and specify the information to be contested, and state the corrective action sought and the reasons for the correction, with supporting justification. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Individuals and newspaper clippings.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09–25–0091

SYSTEM NAME:

Administration: General Files on Employees, Donors and Correspondents, HHS/NIH/NEI.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

National Institutes of Health, Building 31, Room 6A03, 9000 Rockville Pike, Bethesda, MD 20892.

Write to System Manager at the address below for the address of the Federal Records Center where records from this system may be stored.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Donors of gifts, employees, correspondents of the National Eye Institute (NEI).

CATEGORIES OF RECORDS IN THE SYSTEM:

Budget, administrative services, correspondence.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 USC 289i.

PURPOSE(S) OF THE SYSTEM:

(1) To identify certain donors of unconditional gifts to the National Eye Institute; (2) To record certain delegations and permit holders; (3) To maintain a mailing list of persons in the vision research community; (4) To provide service or information to specific requesters; (5) To communicate with collaborating investigators in vision research.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

2. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored in file folders.

RETRIEVABILITY:

Records are retrieved by name and subject area.

SAFEGUARDS:

1. Authorized Users: Employees who maintain records in this system are instructed to grant regular access only to staff with designated responsibilities directly related to the purpose for which the records are kept. Other one-time and special access by other employees is granted on a need-to-know basis as specifically authorized by the system manager.

2. Physical Safeguards: Records are kept in locked offices.

3. Procedural Safeguards: Access to files is strictly controlled. Records may be removed from files only at the request of the system manager or other authorized employee.

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), items: 1100–M–1; 1700–C–1; and, 1900–F–3. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER AND ADDRESS:

National Eye Institute, Executive Officer, Building 31, Room 6A07A, 9000 Rockville Pike, Bethesda, MD 20892.

NOTIFICATION PROCEDURE:

To determine if a record exists, write to: National Eye Institute, Records Management Officer, Building 31, Room 6A17, 9000 Rockville Pike, Bethesda, MD 20892.

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

RECORD ACCESS PROCEDURE:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Contact the official under notification procedures above, and reasonably identify the record and specify the information to be contested, and state the corrective action sought and the reasons for the correction, with supporting justification. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Individuals.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09-25-0099

SYSTEM NAME:

Clinical Research: Patient Medical Records, HHS/NIH/CC.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

National Institutes of Health, Patient Medical Records, Building 10, Room 1N208, 9000 Rockville Pike, Bethesda, MD 20892

and at private organizations under contract. Write to the system manager for a list of current locations.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Registered Clinical Center patients. Some individuals not registered as patients but seen in Clinical Center for diagnostic tests.

CATEGORIES OF RECORDS IN THE SYSTEM:

Medical treatment records.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 USC 241, 248: "Research and Investigation," and "Hospitals, Medical Examinations, and Medical Care."

PURPOSES(S) OF THE SYSTEM:

(1) To provide a continuous history of the treatment afforded individual patients in the Clinical Center; (2) To provide a data base for the clinical research conducted within the hospital.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Information may be used to respond to Congressional inquiries for constituents concerning their admission to NIH Clinical Center.

2. Social Work Department may give pertinent information to community agencies to assist patients or their families.

3. Referring physicians receive medical information for continuing patient care after discharge.

4. Information regarding diagnostic problems, or having unusual scientific value may be disclosed to appropriate medical or medical research organizations or consultants in connection with treatment of patients or in order to accomplish the research purposes of this system. For example, tissue specimens may be sent to the Armed Forces Institute of Pathology; X-rays may be sent for the opinion of a radiologist with extensive experience in a particular kind of diagnostic radiology. The recipients are required to maintain Privacy Act safeguards with respect to these records.

5. Records may be disclosed to representatives of the Joint Commission on Accreditation of Hospitals conducting inspections to ensure that the quality of Clinical Center medical record-keeping meets established standards.

6. Certain diseases and conditions, including infectious diseases, may be reported to appropriate representatives of State or Federal Government as required by State or Federal law.

7. Medical information may be disclosed to tumor registries for maintenance of health statistics.

8. The Department contemplates that it may contract with a private firm for transcribing, updating, copying, or otherwise refining records in this system. Relevant records will be disclosed to such a contractor. The contractor will be required to comply with the requirements of the Privacy Act with respect to such records.

9. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example in defending against a claim based upon an individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that agency to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

10. (a). PHS may inform the sexual and/or needle-sharing partner(s) of a subject individual who is infected with the human immunodeficiency virus (HIV) of their exposure to HIV, under the following circumstances: (1)The information has been obtained in the course of clinical activities at PHS facilities carried out by PHS personnel or contractors; (2)The PHS employee or contractor has made reasonable efforts to counsel and encourage the subject individual to provide the information to the individual's sexual or needle-sharing partner(s); (3) The PHS employee or contractor determines that the subject individual is unlikely to provide the information to the sexual or needle-sharing partner(s) or that the provision of such information cannot reasonably be verified; and (4) The notification of the partner(s) is made, whenever possible, by the subject individual's physician or by a professional counselor and shall follow standard counseling practices.

(b). PHS may disclose information to State or local public health departments, to assist in the notification of the subject individual's sexual and/or needle-sharing partner(s), or in the verification that the subject individual has notified such sexual or needle-sharing partner(s).

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored in file folders and/or on microfiche, and on computer tapes.

RETRIEVABILITY:

Records are retrieved by unit number and patient name.

SAFEGUARDS:

Measures to prevent unauthorized disclosures are implemented as appropriate for each location and for the particular records maintained in each project. Each site implements personnel, physical, and procedural safeguards such as the following:

1. Authorized Users: Employees maintaining records in this system are instructed to grant regular access only to physicians and dentists and other health

care professionals officially participating in patient care, to contractors, or to NIH researchers specifically authorized by the system manager.

2. Physical Safeguards: All record facilities are locked when system personnel are not present.

3. Procedural Safeguards: Access to files is strictly controlled by the system manager. Records may be removed only by system personnel following receipt of a request signed by an authorized user. Access to computerized records is controlled by the use of security codes known only to the authorized user. Codes are user- and function-specific.

Contractor compliance is assured through inclusion of Privacy Act requirements in contract clauses, and through monitoring by contract and project officers. Contractors who maintain records in this system are instructed to make no disclosure of the records except as authorized by the system manager.

These practices are in compliance with the standards of Chapter 45–13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45–13, and Part 6, "ADP Systems Security," of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 3000–E–22, which allows records to be kept until no longer needed for scientific reference. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER AND ADDRESS:

Chief, Medical Record Department, National Institutes of Health, Building 10, Room 1N208, 9000 Rockville Pike, Bethesda, Md. 20892.

NOTIFICATION PROCEDURE:

To determine if a record exists, write to the system manager at the above address. The requester must provide tangible proof of identity, such as a driver's license. If no identification papers are available, the requester must verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

An individual who requests notification of or access to a medical/dental record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion. The representative may be a physician, or other health professional, or other responsible individual. The subject individual will be granted direct access unless it is determined that such access is likely to have an adverse effect on him or her. In that case, the medical/dental record will be sent to the designated representative.

The individual will be informed in writing if the record is sent to the representative.

A parent or guardian who requests notification of or access to a child's/incompetent person's record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the child/incompetent person as well as his/her own identity.

RECORD ACCESS PROCEDURE:

Same as notification procedures. Requesters should also reasonably identify the specific reports and related dates pertaining to the information to be released. There may be a fee for reproducing more than 20 pages of material. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Contact the system manager and reasonably identify the record and specify the information to be contested, and state the corrective action sought and your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely or irrelevant. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Referring physicians, other medical facilities (with patient's consent), patients, relatives of patients.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT.

None.

09–25–0100

SYSTEM NAME:

Clinical Research: Neuropharmacology Studies, HHS/NIH/NINDS.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Building 36, Room 5A06, 9000 Rockville Pike, Bethesda, MD 20892.

Write to System Manager at the address below for the address of the Federal Records Center where records are stored.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Patients in National Institute of Neurological and Communicative Disorders and Stroke (NINDS) related studies concerning aspects of neuropharmacology.

CATEGORIES OF RECORDS IN THE SYSTEM:

Medical data.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 USC 241, 289a, 289c.

PURPOSE OF THE SYSTEM:

Clinical research on the pharmacology in various diseases of the central nervous system and on the effectiveness and action of drugs as given to treat these diseases.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure may be made to HHS contractors, grantees and collaborating researchers and their staff in order to accomplish the research purpose for which the records are collected. The recipients are required to protect such records from improper disclosure.

2. Information may be used to respond to Congressional inquiries for constituents concerning admission to the NIH Clinical Center. Certain diseases and conditions, including infectious diseases, may be reported to appropriate representative of State or Federal Government as required by State or Federal law.

3. Referrals may be made of assignments of research investigators and project monitors to specific research projects to the Smithsonian Institution to contribute to the Smithsonian Science Information Exchange, Inc.

4. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored in laboratory notebooks, file folders and on index cards.

RETRIEVABILITY:

Records are retrieved by name, diagnosis, date of laboratory determination.

SAFEGUARDS:

1. Authorized Users: Employees who maintain records in this system are instructed to grant access only to physicians and scientists working within a specific NIH laboratory.

2. Physical Safeguards: Records are kept in a cabinet and locations which are locked during non-working hours.

3. Procedural Safeguards: Persons having access to the system are trained in Privacy Act requirements. Records are used either in the system location or a designated work area. Records are returned to cabinets at the end of each working day. System location is attended at all times during working hours.

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 3000–G–3, which allows records to be kept as long as they are useful in scientific research. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER AND ADDRESS:

Director, Division of Intramural Research, NINDS, Building 10, Room 5N214, NIH, 9000 Rockville Pike, Bethesda, MD 20892.

NOTIFICATION PROCEDURE:

To determine if a record exists write to: Chief, Administrative Services Branch, Building 31, Room 8A49, NIH, 9000 Rockville Pike, Bethesda, MD 20892.

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

An individual who requests notification of or access to a medical/dental record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

RECORD ACCESS PROCEDURE:

Same as notification procedures.

Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Contact the official at the address specified under notification procedures above, and reasonably identify the record and specify the information to be contested, and state the corrective action sought and the reasons for the correction. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Other medical, scientific and educational institutions; individual physicians in private practice.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09–25–0108

SYSTEM NAME:

Personnel: Guest Researchers/Student Scientists/Special Volunteers/Scientists Emeriti, HHS/NIH/DPM.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

National Institutes of Health, Office of the Associate Director for Intramural Affairs, Building 1, Room 103, 9000 Rockville Pike, Bethesda, MD. 20892.

Systems and Actions Branch, Division of Personnel Management, Building 31, Room B3C27, 9000 Rockville Pike, Bethesda, MD 20892.

Personnel and Administrative Offices of the National Institutes of Health (NIH).

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals using NIH facilities who are not NIH employees.

CATEGORIES OF RECORDS IN THE SYSTEM:

Personal information including name, address, date and place of birth, education, employment, purpose for which NIH facilities are desired, outside sponsor, and NIH sponsor.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 U.S.C. 241(a)(2), 42 U.S.C. 282(b)(10), and 42 U.S.C. 284(b)(1)(k).

PURPOSE OF THE SYSTEM:

To determine eligibility to use NIH facilities, to document the individual's presence at NIH, and to record that the individual is not an employee.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure may be made to U.S. Office of Personnel Management for program evaluation purposes; to General Accounting Office for fund disbursement determinations.

2. Disclosure may be made to institutions providing financial support.

3. Disclosure may be made to a congressional office from the record of an individual in response to a verified inquiry from the congressional office made at the request of that individual.

4. Disclosure may be made to the Department of Justice or to a court or other tribunal, when (a) HHS, or any component thereof; or (b) any HHS employee in his or her official capacity; or (c) any HHS employee in his or her individual capacity where the Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the employee; or (d) the United States or any agency thereof where HHS determines that the litigation is likely to affect HHS or any of its components, is a party to litigation or has any interest in such litigation, and HHS determines that the use of such records by the Department of Justice, court or other tribunal is relevant and necessary to the litigation and would help in the effective representation of

the governmental party, provided, however that in each case, HHS determines that such disclosure is compatible with the purpose for which the records were collected.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

File folders.

RETRIEVABILITY:

Records are retrieved by name.

SAFEGUARDS:

For each location and for the particular records maintained in each project. Each site implements personnel, physical and procedural safeguards such as the following:

1. Authorized Users: Access is granted only to personnel staff, administrative office staff and management officials directly involved in the administration of the Guest Researcher, Special Volunteer and Scientist Emeriti programs.

2. Physical Safeguards: Record facilities are locked when system personnel are not present.

3. Procedural Safeguards: Access to files is strictly controlled by system personnel. Records may be removed from the file only with the approval of the system manager or other authorized employees.

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 2300–320–3(a), which allows records to be destroyed after a maximum period of 2 years after the individual completes work at NIH. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER AND ADDRESS:

National Institutes of Health, Chief, Systems and Actions Branch, Division of Personnel Management, Building 31, Room B32C07, 9000 Rockville Pike, Bethesda, MD 20892.

NOTIFICATION PROCEDURE:

To determine if a record exists and where it is located, contact: National Institutes of Health, Division of Personnel Management, Privacy Act Coordinator, Building 31, Room 1C39, 9000 Rockville Pike, Bethesda, MD 20892.

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

RECORD ACCESS PROCEDURE:

Contact the Personnel Officer or Administrative Officer in whose office the record is located and provide verification of identity as described under notification procedure above. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Write to the official specified under notification procedures above, and reasonably identify the record and specify the information being contested, the corrective action sought, and your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely or irrelevant. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Subject individual, NIH sponsor, funding institution.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09–25–0112

SYSTEM NAME:

Grants and Cooperative Agreements: Research, Research Training, Fellowship and Construction Applications and Related Awards, HHS/NIH/OD.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

See Appendix I.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Grant applicants and Principal Investigators; Program Directors; Institutional and Individual Fellows; Research Career Awardees.

CATEGORIES OF RECORDS IN THE SYSTEM:

Grant applications and review history, awards, financial records, progress reports and related correspondence.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

"Research and Investigation," "National Library of Medicine," "National Cancer Institute," "National Heart, Lung and Blood Institute," "National Institute of Dental Research," "National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases," "National Institute of Neurological Diseases and Stroke, and Other Institutes," "National Institute of Child Health and Human Development," "National Institute of General Medical Sciences," "National Eye Institute," and "National Institute on Aging," of the Public Health Service Act, (42 U.S.C. 241, 276, 281, 287, 288, 289(a), (d), (e), (i), 289(k–2)).

PURPOSE(S) OF THE SYSTEM:

1. Information provided is used by NIH staff for review, award, and administration of grant programs.

2. Information is also used to maintain communication with former fellows who have incurred an obligation through the National Research Service Award Program.

3. Staff may also use curriculum vitae to identify candidates who may serve as ad hoc consultants or committee and council members in the grant peer review process.

4. As a part of the cost analysis of a proposed grant, a budget review is conducted of the percentage of time and effort listed under personnel category, equipment and supply categories, and other items listed under "other" category.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure may be made of assignments of research investigators and project monitors to specific research projects to the National Technical Information Service (NTIS), Department of Commerce, to contribute to the Smithsonian Science Information Exchange, Inc.

2. Disclosure may be made to the cognizant audit agency for auditing.

3. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the

Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected.

4. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

5. Disclosure may be made to qualified experts not within the definition of Department employees as prescribed in Department Regulations, 45 CFR 56.2, for opinions as a part of the application review and award administration processes.

6. Disclosure may be made to a Federal agency, in response to its request, in connection with the letting of a contract, or the issuance of a license, grant or other benefit by the requesting agency, to the extent that the record is relevant and necessary to the requesting agency's decision on the matter.

7. A record may be disclosed for a research purpose, when the Department: (A) has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected; or obtained; (B) has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring; (C) has required the recipient to (1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except (a) in emergency circumstances affecting the health or safety of any individual, (b) for use in another research project, under these same conditions, and with written authorization of the Department, (c) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (d) when required by law; (D) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by these provisions.

8. Disclosure may be made to a private firm for the purpose of collating, analyzing, aggregating or otherwise refining records in a system. Relevant records will be disclosed to such a contractor. The contractor shall be required to maintain Privacy Act safeguards with respect to such records;

9. Disclosure may be made to the grantee institution in connection with the review of an application or performance or administration under the terms and conditions of the award, or in connection with problems that might arise in performance or administration if an award is made on a grant proposal.

10. Disclosure may be made to the profit institution's president or official responsible for signing the grant application in connection with the review or award of a grant application and in connection with the administration and performance of a grant under the terms and conditions of the awards.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

Disclosures pursuant to 5 U.S.C. 552a(b)(12):

Disclosures may be made from this system to "consumer reporting agencies" as defined in the Fair Credit Reporting Act (15 U.S.C. 1681a(f)) or the Federal Claims Collection Act of 1966 (31 U.S.C. 3701(a)(3)).

The Department may disclose to consumer reporting agencies information on individuals who have failed to meet payback obligations incurred under awards made under authority of the National Research Service Awards Program (41 U.S.C. 2891–1). Information disclosed includes data identifying the individual, the amount, status and history of the obligation, and that the obligation arose from an award made under the National Research Service Awards Program.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Stored in file folders, on computer tapes and discs, cards and in notebooks.

RETRIEVABILITY:

Retrieved by name and grant number.

SAFEGUARDS:

A variety of physical and procedural safeguards are implemented, as appropriate, at the various locations of this system:

1. Authorized Users: Employees who maintain records in this system are instructed to grant regular access only to officials whose duties require use of the information. These officials include review groups, grants management staff, other extramural program staff, health scientist administrators, data processing and analysis staff and management officials with oversight responsibilities for extramural programs. Other one-time and special access is granted on an individual basis as specifically authorized by the system manager. Authorization for access to computerized files is controlled by the system manager or designated official and is granted on a need-to-know basis. Lists of authorized users are maintained.

2. Physical Safeguards: Secured facilities, locked rooms, locked cabinets, personnel screening; records stored in order of grant numbers which are randomly assigned.

3. Procedural Safeguards: Access to file rooms and files is strictly controlled by files staff or other designated officials; charge-out cards identifying users are required for each file used; inactive records are transferred to controlled storage in Federal Records Center in a timely fashion; retrieval of records from inactive storage is controlled by the system manager or designated official and by the NIH Records Management Officer; computer files are password protected and access is actively monitored by the Computer Center to prevent abuse. Employees are given specialized training in the requirements of the Privacy Act as applied to the grants program.

These particular safeguards are developed in accordance with Chapter 45–13, "Safeguarding Records Contained in Systems of Records," of the HHS General Administration Manual, supplementary Chapter PHS hf: 45–13, and Part 6, "ADP Systems Security", of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), items: 4000–B–1; 4000–B–4; 4000–C–1 and, 4600–D–1. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER AND ADDRESS:

See Appendix II.

NOTIFICATION PROCEDURE:

Write to official at the address specified in Appendix II to determine if a record exists. The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

RECORD ACCESS PROCEDURE:

Write to the official at the address specified in Appendix IV to obtain access to a record, and provide the same information as is required under the Notification Procedures above. Requesters should also reasonably specify the record contents being sought.

Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Contact the official at the address specified in Appendix II, and reasonably identify the record and specify the information being contested, the corrective action sought, and your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely or irrelevant. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Information submitted by applicant; supplemented by outside reviewers and internal staff.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

Appendix I—System Location

National Cancer Institute, Executive Plaza South, Suite T–42, 6120 Executive Boulevard, Bethesda, MD 20892.
National Heart, Lung, and Blood Institute, Westwood Building, Room 4A09, 5333 Westbard Avenue, Bethesda, MD 20892.
National Library of Medicine, Building 38A, Room 5N509, 8600 Rockville Pike, Bethesda, MD 20894.
National Institute of Allergy and Infectious Diseases, Chief, Grants Management Branch, DEA, Control Data Bldg., Room 4B–21, 6003 Executive Blvd., Rockville, MD 20892.
National Institute of Allergy and Infectious Diseases, Chief, Management Information Systems Section, FMISB, OAM, Westwood Building, Room 733, 5333 Westbard Avenue, Bethesda, MD 20892.
National Institute of Diabetes and Digestive and Kidney Diseases, Westwood Building, Room 610, 5333 Westbard Avenue, Bethesda, MD 20892.
National Institute of Arthritis and Musculoskeletal and Skin Diseases, Westwood Building, Room 5A03, 5333 Westbard Avenue, Bethesda, MD 20892.
National Institute of Child Health and Human Development, Landow Building, Room 6A21, 7910 Woodmont Avenue, Bethesda, MD 20892.
National Institute on Aging, Gateway Building, Room 2N–212, 7201 Wisconsin Avenue, Bethesda, MD 20892.
National Institute of Dental Research, Grants Management Officer, Westwood Building, Room 518, Bethesda, MD 20892.
National Institute of Environmental Health Sciences, Grants Management Officer, Building 2, Room 204, 104 Alexander Drive, Research Triangle Park, NC 27709.
National Institute of General Medical Sciences, Grants Management Officer, Westwood Building, Room 953, 5333 Westbard Avenue, Bethesda, MD 20892.
National Institute of Neurological Disorders and Stroke, Federal Building, Room 10A12, 7550 Wisconsin Avenue, Bethesda, MD 20892.
National Institute on Deafness and Other Communication Disorders, Room 400B, Executive Plaza South, 620 Executive Boulevard, Rockville, MD 20852.
National Eye Institute, Building 31, Room 6A47, 9000 Rockville Pike, Bethesda, MD 20892.
National Center for Research Resources, Westwood Building, Room 853, 5333 Westbard Avenue, Bethesda, MD 20892.
National Center for Nursing Research, Building 31, Room 5B06, 9000 Rockville Pike, Bethesda, MD 20892.
Washington National Records Center, 4205 Suitland Road, Suitland, MD 20409.

Appendix II—System Manager and Address

National Cancer Institute, Grants Management Analyst, Executive Plaza South, Suite 234, 6120 Executive Boulevard, Bethesda, MD 20892.
National Heart, Lung, and Blood Institute, Chief, Grants Operations Branch, Division of Extramural Affairs, Westwood Building, Room 4A10, 5333 Westbard Avenue, Bethesda, MD 20892.
National Heart, Lung, and Blood Institute, Administrative Officer, Division of Extramural Affairs, Westwood Building, Room 7A11, Bethesda, MD 20892.
National Library of Medicine, Associate Director for Extramural Programs, Building 38A, Room 5N505, 8600 Rockville Pike, Bethesda, MD 20894.
National Institute of Allergy and Infectious Diseases, Chief, Grants Management Branch, DEA, Control Data Bldg., Room 4B–21, 6003 Executive Blvd., Rockville, MD 20892.
National Institute of Allergy and Infectious Diseases, Chief, Management Information Systems Section, FMISB, OAM, Westwood Building, Room 733, 5333 Westbard Avenue, Bethesda, MD 20892.
National Institute of Arthritis and Musculoskeletal and Skin Diseases, Grants Management Officer, Westwood Building, Room 407, 5333 Westbard Avenue, Bethesda, MD 20892.
National Institute of Diabetes and Digestive and Kidney Disease, Grants Management Officer, Room 639, Westwood Building, 5333 Westbard Avenue, Bethesda, MD 20892.
National Institute of Child Health and Human Development, Chief, Office of Grants & Contracts, Executive Plaza North Room 501, 6130 Executive Building, Bethesda, MD 20892.
National Institute on Aging, Grants Management Officer, Gateway Building, Room 2N–212, 7201 Wisconsin Avenue, Bethesda, MD 20892.
National Institute of Dental Research, Grants Management Officer, NIDR, Westwood Building, Room 518, 5333 Westbard Avenue, Bethesda, MD 20892.
National Institute of Environmental Health Sciences, Grants Management Officer, Building 2, Room 204, 104 Alexander Drive, Research Triangle Park, NC 27709.
National Institute of General Medical Sciences, Grants Management Officer, NIGMS, Westwood Building, Room 953, Bethesda, MD 20892.
National Institute of Neurological Disorders and Stroke, Grants Management Officer, Federal Building, Room 1004A, Bethesda, MD 20892.
National Institute on Deafness and Other Communication Disorders, Grants Management Officer, Executive Plaza South, Room 400B, 630 Executive Boulevard, Rockville, MD 20852.
National Center for Nursing Research, Grants Management Officer, Building 31, Room 5B06, 9000 Rockville Pike, Bethesda, MD 20892.
National Eye Institute, Grants Management Officer, Building 31, Room 6A48, 9000 Rockville Pike, Bethesda, MD 20892.
National Center for Research Resources, Director, Office of Grants and Contracts Management, Westwood Building, Room 853, 5333 Westbard Avenue, Bethesda, MD 20892.

Appendix III—Notification Procedures

National Cancer Institute, See Appendix II.
National Heart, Lung, and Blood Institute, Privacy Act Coordinator, Building 31, Room 5A08, Bethesda, MD 20892.
National Library of Medicine, See Appendix II.
National Institute of Allergy and Infectious Diseases, See Appendix II.
National Institute of Diabetes and Digestive and Kidney Diseases, Administrative Officer, Building 31, Room 9A46, 9000 Rockville Pike, Bethesda, MD 20892.
National Institute of Child Health and Human Development, See Appendix II.
National Institute of Aging, See Appendix II.
National Institute of Dental Research, NIDR Privacy Act Coordinator, Building 31, Room 2C–35, 9000 Rockville Pike, Bethesda, MD 20892.
National Institute of Environmental Health Sciences, See Appendix II.
National Institute of General Medical Sciences, See Appendix II.

National Institute of Neurological Disorders and Stroke, See Appendix II.
National Institute on Deafness and Other Communication Disorders, See Appendix II.
National Eye Institute, See Appendix II.
National Center for Nursing Research. See Appendix II.
National Center for Research Resources, See Appendix II.

Appendix IV—Records Access Procedures

National Cancer Institute, Privacy Act Coordinator, Building 31, Room 10A30, 9000 Rockville Pike, Bethesda, MD 20892.
National Heart, Lung, and Blood Institute, See Appendix III.
National Library of Medicine, See Appendix II.
National Institute of Allergy and Infectious Diseases, Privacy Act Coordinator, Control Data Bldg., Room 4C–01, Rockville, MD 20892.
National Institute of Diabetes and Digestive and Kidney Diseases, See Appendix II.
National Institute of Child Health and Human Development, See Appendix II.
National Institute on Aging, See Appendix II.
National Institute of Dental Research, Grants Management Officer, Westwood Building, Room 518, 5333 Westbard Avenue, Bethesda, MD 20892.
National Institute of Environmental Health Sciences, See Appendix II.
National Institute of General Medical Sciences, Privacy Act Coordinator, Westwood Building, Room 9A05, Bethesda, MD 20892.
National Institute of Neurological Disorders and Stroke, Chief, Administrative Services Branch, Building 31, Room 8A49, 9000 Rockville Pike, Bethesda, MD 20892.
National Institute on Deafness and Other Communication Disorders, Chief, Administrative Management Branch, Building 31, Room 3C21, 9000 Rockville Pike, Bethesda, MD 20892.
National Eye Institute, Administrative Officer, Building 31, Room 6A31, 9000 Rockville Pike, Bethesda, MD 20892.
National Center for Research Resources, Privacy Act Coordinator, Westwood Building, Room 10A15, 5333 Westbard Avenue, Bethesda, MD 20892.

09–25–0115

SYSTEM NAME:

Administration: Curricula Vitae of Consultants and Clinical Investigators, HHS/NIH/NIAID.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

National Institutes of Health, Control Data Bldg., Room 3A01, 6003 Executive Blvd., Bethesda, MD 20892.

Write to System Manager at the address below for the address of the Federal Records Center where records are stored.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Consultants and Clinical Investigators under National Institute of Allergy and Infectious Diseases (NIAID) Investigational New Drug Applications.

CATEGORIES OF RECORDS IN THE SYSTEM:

Curriculum vitae.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 U.S.C. 241, 289a.

PURPOSE OF THE SYSTEM:

(1) To maintain a record of the investigators under Investigational New Drug (IND) applications. (2) To appoint consultants to the Clinical Research Subpanel (CRS).

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

2. The Department of Health and Human Services (HHS) may disclose information from this system of records to the Department of Justice, or to a court or other tribunal, when (a) HHS, or any component thereof; or (b) any HHS employee in his or her official capacity; or (c) any HHS employee in his or her individual capacity where the Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the employee; or (d) the United States or any agency thereof where HHS determines that the litigation is likely to affect HHS or any of its components, is a party to litigation or has any interest in such litigation, and HHS determines that the use of such records by the Department of Justice, court or other tribunal is relevant and necessary to the litigation and would help in the effective representation of the governmental party, provided, however that in each case, HHS determines that such disclosure is compatible with the purpose for which the records were collected.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Stored in books.

RETRIEVABILITY:

Retrieved by name.

SAFEGUARDS:

Measures to prevent unauthorized disclosures are implemented as appropriate for each location and for the particular records maintained in each project. Each site implements personnel, physical, and procedural safeguards such as the following:

1. Authorized Users: Employees who maintain records in this system are instructed to grant regular access only to NIAID staff whose duties require the use of such information. Authorized users are located in the Clinical and Regulatory Affairs Section, Division of Microbiology and Infectious Diseases, NIAID. Other one-time and special access by other employees is granted on a need-to-know basis as specifically authorized by the system manager.

2. Physical Safeguards: Building is locked during off-duty hours.

3. Procedural Safeguards: Access to files is strictly controlled by files staff. Records may be removed from files only at the request of the system manager or other authorized employee.

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 1100–G. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER AND ADDRESS:

Chief, Clinical and Regulatory Affairs Section, DMID, NIAID, Control Data Bldg., Room 3A–01, 6003 Executive Blvd., Rockville, MD 20892.

NOTIFICATION PROCEDURE:

To determine if a record exists, write to: NIAID Privacy Act Coordinator, Control Data Bldg., Room 4C–01, 6003 Executive Blvd. Rockville, MD 20892.

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

RECORD ACCESS PROCEDURE:

Same as record notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Write to the official specified under notification procedures above, and

reasonably identify the record and specify the information being contested, the corrective action sought, and your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely or irrelevant. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Individuals.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09-25-0118

SYSTEM NAME:

Contracts: Professional Services Contractors, HHS/NIH/NCI.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Building 31, Room 3A52, DCT, 9000 Rockville Pike, Bethesda, MD 20892.

Building 31, Room 3A22, OD, 9000 Rockville Pike, Bethesda, MD 20892.

Building 31, Room 10A10, DEA, 9000 Rockville Pike, Bethesda, MD 20892.

Building 31, Room 3A05, DCBDC, 9000 Rockville Pike, Bethesda, MD 20892.

Building 31, Room 11A11, DCE, 9000 Rockville Pike, Bethesda, MD 20892.

Building 31, Room 10A50, DCPC, 9000 Rockville Pike, Bethesda, MD 20892.

Write to System Manager at the address below for the address of the Federal Records Center where records may be stored.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals under contract with the National Cancer Institute.

CATEGORIES OF RECORDS IN THE SYSTEM:

Professional Services Contracts.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 USC 241(d), 281.

PURPOSE OF THE SYSTEM:

Used by staff for general administrative purposes to assure compliance with contract program requirements.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

2. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Stored in file folders.

RETRIEVABILITY:

Retrieved by name.

SAFEGUARDS:

1. Authorized Users: Access is limited to authorized personnel (system manager and staff).

2. Physical Safeguards: Records are maintained in offices which are locked when not in use.

3. Procedural Safeguards: Access to files is strictly controlled by system manager and staff.

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual, Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B-361), item 2600-A-4, which allows records to be destroyed after a maximum period of 6 years and 3 months after final payment. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER AND ADDRESS:

Administrative Officer, DCT, Building 31, Room 3A52, 9000 Rockville Pike, Bethesda, MD 20892.

Administrative Officer, OD, National Institutes of Health, Building 31, Room 11A35, 9000 Rockville Pike, Bethesda, MD 20892.

Administrative Officer, DEA, Building 31, Room 10A10, 9000 Rockville Pike, Bethesda, MD 20892.

Administrative Officer, DCBDC, Building 31, Room 3A05, 9000 Rockville Pike, Bethesda, MD 20892.

Administrative Officer, DCE, Building 31, Room 11A11, 9000 Rockville Pike, Bethesda, MD 20892.

Administrative Officer, DCPC, Building 31, Room 10A50, 9000 Rockville Pike, Bethesda, MD 20892.

NOTIFICATION PROCEDURE:

Write to the appropriate System Manager listed above to determine if a record exists. The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

RECORD ACCESS PROCEDURE:

Same as notification procedures.

Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Contact the official under notification procedures above, and reasonably identify the record and specify the information to be contested, and state the corrective action sought and the reasons for the correction, with supporting justification. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Individuals in the system.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09-25-0121

SYSTEM NAME:

International Activities: Senior International Fellowships Program, HHS/NIH/FIC.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

National Institutes of Health, Building 31, Room B2C39, 9000 Rockville Pike, Bethesda, MD, 20892.

Write to System Manager at the address below for the address of the Federal Records Center where records from this system are stored.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Applicants for Senior International Fellowships.

CATEGORIES OF RECORDS IN THE SYSTEM:

Applications and associated records and reports.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 U.S.C. 242 e.

PURPOSE OF THE SYSTEM:

For award and administration of fellowships to outstanding faculty members in midcareer from U.S biomedical research and educational institutions for study abroad.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Each fellow's home institution receives a notice of award and funding for the fellowship.

2. Applications are made available to authorized employees and agents of the US, including the General Accounting Office for purposes of investigations, inspections and audits, and in appropriate cases, to the Department of Justice for proper action under civil and criminal laws.

3. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

4. The Department of Health and Human Services (HHS) may disclose information from this system of records to the Department of Justice, or to a court or other tribunal, when (a) HHS, or any component thereof; or (b) any HHS employee in his or her official capacity; or (c) any HHS employee in his or her individual capacity where the Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the employee; or (d) the United States or any agency thereof where HHS determines that the litigation is likely to affect HHS or any of its components, is a party to litigation or has any interest in such litigation, and HHS determines that the use of such records by the Department of Justice, court or other tribunal is relevant and necessary to the litigation and would help in the effective representation of the governmental party, provided, however that in each case, HHS determines that such disclosure is compatible with the purpose for which the records were collected.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

File folders and computer discs.

RETRIEVABILITY:

Name and fellowship number.

SAFEGUARDS:

Measures to prevent unauthorized disclosures are implemented as appropriate for each location and for the particular records maintained in each project. Each site implements personnel, physical, procedural safeguards such as the following:

1. Authorized Users: Employees who maintain records in this system are instructed to grant regular access only to Fogarty International Center (FIC) program staff. Other one-time and special access by other employees is granted on a need-to-know basis as specifically authorized by the system manager.

2. Physical Safeguards. The records are stored in locked file cabinets and offices are locked during off-duty hours.

3. Procedural Safeguards. Access to files is strictly controlled by files staff. Records may be removed from files only at the request of the system manager or other authorized employees. For computerized records access is controlled by the use of security codes known to authorized users and access codes are changed periodically. The computer system maintains an audit record of all requests for access.

These practices are in compliance with the standards of Chapter 45–13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45–13, and Part 6, "ADP Systems Security," of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 2300–320–7, which allows records to be destroyed after a maximum period of 6 years after the close of a case. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER AND ADDRESS:

Chief, International Research Awards Branch, Fogarty International Center, National Institutes of Health, Building 31, Room B2C39, 9000 Rockville Pike, Bethesda, Md. 20892.

NOTIFICATION PROCEDURE:

Requests for notification of or access to records should be addressed to the system manager, listed above. The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a 5,000 dollar fine.

RECORD ACCESS PROCEDURE:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Contact the official under notification procedures above, and reasonably identify the record and specify the information to be contested, and state the corrective action sought and the reasons for the correction. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Information obtained from applicants and persons supplying recommendations through the Division of Research Grants.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09–25–0124

SYSTEM NAME:

Administration: Pharmacology Research Associates, HHS/NIH/NIGMS.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

National Institutes of Health, Westwood Building, Room 919, 5333 Westbard Avenue, Bethesda, MD 20892.

Write to System Manager at the address below for the address of the Federal Records Center where records are stored.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Applicants for positions as Pharmacology Research Associates with the Institutes of General Medical Sciences (NIGMS).

CATEGORIES OF RECORDS IN THE SYSTEM:

Individual application forms, academic transcripts, reprints and references, curriculum vitae and salary adjustment memorandum for fellows.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 U.S.C. 209.

PURPOSE(S) OF THE SYSTEM:

For review, award and administration of the Pharmacology Research Associate Program (PRAT).

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

2. The Department of Health and Human Services (HHS) may disclose information from this system of records to the Department of Justice, or to a court or other tribunal, when (a) HHS, or any component thereof; or (b) any HHS employee in his or her official capacity; or (c) any HHS employee in his or her individual capacity where the Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the employee; or (d) the United States or any agency thereof where HHS determines that the litigation is likely to affect HHS or any of its components, is a party to litigation or has any interest in such litigation, and HHS determines that the use of such records by the Department of Justice, court or other tribunal is relevant and necessary to the litigation and would help in the effective representation of the governmental party, provided, however that in each case, HHS determines that such disclosure is compatible with the purpose for which the records were collected.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

File folders.

RETRIEVABILITY:

By name of applicant.

SAFEGUARDS:

Measures to prevent unauthorized disclosures are implemented as appropriate for each location and for the particular records maintained in each project. Each site implements personnel, physical, and procedural safeguards such as the following:

1. Authorized Users: Employees who maintain the system are instructed to grant access only to authorized personnel (System Manager and staff assigned to the program).

2. Physical Safeguards: The records are maintained in locked file cabinets when not in use and system location is locked during non-working hours.

3. Procedural Safeguards: Access to files is strictly controlled by responsible individuals who have been instructed in the Privacy Act requirements. Records are returned to the locked cabinets when not in use.

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 2300–320–2(a). Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER AND ADDRESS:

Director, PRAT Program, Pharmacological Sciences, NIGMS Westwood Building Room 919, Bethesda, MD 20892.

NOTIFICATION PROCEDURE:

To determine if a record exists, write to System Manager and provide the following information: applicant's name and date of application.

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

RECORD ACCESS PROCEDURE:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought.

Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Contact the official at the address specified under notification procedure above, and reasonably identify the record, and specify the information to be contested, the corrective action sought. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Information obtained from applicants, university registrars, and persons supplying recommendations through the PRAT Program. Salary adjustment memos from preceptors.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09–25–0129

SYSTEM NAME:

Clinical Research: Clinical Research Studies Dealing With Hearing, Speech, Language and Chemosensory Disorders, HHS/NIH/NIDCD.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

National Institute on Deafness and Other Communication Disorders (NIDCD), 6120 Executive Boulevard, Rockville, MD 20852.

And at hospitals, medical centers, universities and educational settings under contract. Inactive records may be stored at a Federal Records Center. A list of locations is available upon request from the System Manager at the address below.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Patients and normal volunteers participating in clinical research studies dealing with hearing, speech, language and chemosensory disorders.

CATEGORIES OF RECORDS IN THE SYSTEM:

Medical findings, clinical research data, medical and educational histories and research data on the hearing, speech, language, cognition and chemosensory systems of subjects being tested.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 U.S.C. 241, 289a, 289c.

PURPOSE OF THE SYSTEM:

Clinical research on the disorders of speech, language, and hearing to discover factors leading to these disorders and to improve prevention, diagnoses, and treatment.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure may be made to HHS contractors, grantees and collaborating researchers and their staff in order to accomplish the research purpose for

which the records are collected. The recipients are required to protect such records from improper disclosure.

2. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

3. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example in defending against a claim based upon an individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, the Department may disclose such records as it deems desirable or necessary to the Department of Justice or other appropriate Federal agency to enable that agency to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored in file folders.

RETRIEVABILITY:

Name or identifier code.

SAFEGUARDS:

1. Authorized Users: Employees who maintain the system are instructed to grant access only to the principal investigator and staff assigned to a particular project, and to other authorized personnel (project officer, contracting officer).

2. Physical Safeguards: Records are locked in cabinets when not in actual use and system location is locked during non-working hours.

3. Procedural Safeguards: Personnel having access to system are trained in Privacy Act requirements. Records are returned to locked file cabinets at end of working day.

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 3000–G–3, which allows records to be kept as long as they are useful in scientific research. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER AND ADDRESS:

Director, Division of Communication Sciences and Disorders, NIDCD Executive, Plaza South, Room 400B, 6120 Executive Boulevard, Rockville, MD 20852.

NOTIFICATION PROCEDURE:

Write to: Chief, Administrative Management Branch, NIDCD, Building 31, Room 3C21, 9000 Rockville Pike, Bethesda, Maryland 20892 and ask if a file exists with your name in studies of the Division of Communication Sciences and Disorders. Please supply the following information:

1. Approximate date and place of examination and/or treatment.

2. Name of the study, if known.

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

An individual who requests notification of or access to a medical record shall, at the time the request is made, designate in writing, a responsible representative, who may be a physician, who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

RECORD ACCESS PROCEDURE:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Write to system manager and reasonably identify the record, specify the information to be contested, and state the corrective action sought and the reasons for the correction. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Information provided by patients, patients' families, hospital records, school records, and clinical investigators.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09–25–0140

SYSTEM NAME:

International Activities: International Scientific Researchers in Intramural Laboratories at the National Institutes of Health, HHS/NIH/FIC.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Fogarty International Center, Building 16A, Room 101, 9000 Rockville Pike, Bethesda, MD 20892, and Division of Computer Research and Technology, Building 12A, Room 3061, National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20892.

Ancillary records are located in the Office of the Associate Director for Intramural Affairs, laboratories, administrative and personnel offices where participants are assigned. Write to System Manager at the address below for the address of the Federal Records Center where records are stored.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Health scientists at all levels of their postdoctoral or equivalent research careers who are invited to the National Institutes of Health for further training or to conduct research in their biomedical specialties under the auspices of FIC's administration of International Activities. Most of these scientists are foreign, however some may be resident aliens or U.S. citizens.

Individuals in these categories include Visiting Associates, Visiting Scientists, Foreign Special Experts who are employees and Visiting Fellows, Guest Researchers, Exchange Scientists, International Research Fellows, Fogarty Scholars, Special Volunteers, Adjunct Scientists and Residents who are not employees.

CATEGORIES OF RECORDS IN THE SYSTEM:

History of fellowship, employment and/or stay at NIH; education, immigration data and references. For payroll purposes, social security numbers are requested of all applicants accepted into the program.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 U.S.C. 242l and Section 307 of the Public Health Service Act.

PURPOSE OF THE SYSTEM:

To document the individual's presence at the NIH, to record immigration

history of the individual in order to verify continued eligibility in existing programs, and to meet requirements in the Code of Federal Regulations (8 CFR, parts 8 and 22, "Aliens and Nationality").

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Information is made available to authorized employees and agents of the U.S. Government including, but not limited to, the General Accounting Office, the Internal Revenue Service, and the FBI and Immigration and Naturalization Service, Department of Justice, for purposes of investigations, inspections and audits.

2. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of the individual.

3. The Department of Health and Human Services (HHS) may disclose information from this system of records to the Department of Justice, or to a court or other tribunal, when (a) HHS, or any component thereof; or (b) any HHS employee in his or her official capacity; or (c) any HHS employee in his or her individual capacity where the Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the employee; or (d) the United States or any agency thereof where HHS determines that the litigation is likely to affect HHS or any of its components, is a party to litigation or has any interest in such litigation, and HHS determines that the use of such records by the Department of Justice, court or other tribunal is relevant and necessary to the litigation and would help in the effective representation of the governmental party, provided, however that in each case, HHS determines that such disclosure is compatible with the purpose for which the records were collected.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored in file folders and on file cards, computer tapes, computer disks and microfilm.

RETRIEVABILITY:

By name, country of citizenship, institution, fellowship number, social security number, visa and immigration status, program category, dates of stay at NIH, NIH component, and home address.

SAFEGUARDS:

A variety of safeguards is implemented for the various sets of records included under this system according to the sensitivity of the data they contain.

1. Authorized Users: NIH administrative and personnel staff screened by FIC staff to access information on a need-to-know basis. Only FIC staff are authorized to add, change, or delete data. Other authorized users may only read data, with the exception of designated computer programmers who have specific permission to make necessary programming changes.

2. Physical Safeguards: The records are maintained in locked file cabinets, and offices are locked during off-duty hours.

3. Procedural Safeguards: Access to files is strictly controlled by files staff. Records may be removed from files only at the request of the system manager or other authorized employees. For computerized records, access is controlled by the use of security codes known only to authorized users; access codes are changed periodically. The computer system maintains an audit record of all requests for access.

These practices are in compliance with the standards of Chapter 45–13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45–13, and Part 6, "ADP Systems Security," of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 2300–320, which allows records to be destroyed after a maximum period of 6 years after the close of a case. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER AND ADDRESS:

Chief, International Services and Communications Branch, Building 16A, Room 101, Fogarty International Center, National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20892.

NOTIFICATION PROCEDURE:

Requests for notification of or access to records should be addressed to the system manager as listed above. Verification of identity is required.

RECORD ACCESS PROCEDURE:

Same as notification procedure. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Contact the official listed under notification procedure above, and reasonably identify the record, and specify the information to be contested, and state the corrective action sought and the reasons for the correction. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD ACCESS CATEGORIES:

Subject individuals and other federal agencies.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09–25–0142

SYSTEM NAME:

Clinical Research: Records of Subjects in Intramural Research, Epidemiology, Demography and Biometry Studies on Aging, HHS/NIH/NIA.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Records included in this system will be located in hospitals and clinics, research centers and research foundations, and in facilities of the National Institute on Aging (NIA) in Bethesda, MD. They may be stored at Federal Records Centers. A list of locations is available upon request from the System Manager.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Participants in these studies will include: (1) Individuals whose physical, genetic, social, psychological, cultural, economic, environmental, behavioral, pharmacological, or nutritional conditions or habits are studied in relationship to the normal aging process and/or diseases and other normal or abnormal physical or psychological conditions of the aged, and (2) normal volunteers who are participants in such studies.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system will consist of a variety of health, demographic, and statistical information resulting from or contained in research findings, medical histories, vital statistics, personal interviews, questionnaires, or direct observations. The system will also include records of current addresses of study participants, and correspondence from or about participants in the studies. When supplied on a voluntary basis, Social Security numbers will also be included.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Authority is provided by Sections 301, Research Contracting, and 463–4, Health Research Extension Act of 1985, Pub. L. 99–158.

PURPOSE(S) OF THE SYSTEM:

The National Institute on Aging will use the data collected; (1) In research projects on (a) the health status of individuals and changes in health status over time, (b) the incidence and prevalence of certain diseases and problems of the aged in certain populations, and (c) the changes that take place as individuals age; (2) and for program planning and evaluation.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Records may be disclosed to HHS contractors, collaborating researchers and their staffs in order to accomplish the basic research purpose of this system. The recipients will be required to maintain Privacy Act safeguards with respect to such records.

2. Data may be disclosed to organizations deemed qualified by the Secretary to carry out quality assessment, medical audits or utilization review.

3. A record may be disclosed for a research purpose, when the Department: (A) Has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained; (B) has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring; (C) has required the recipient to (1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record. (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except (a) in emergency circumstances affecting the health or safety of any individual, (b) for use in another research project, under these same conditions, and with written authorization of the Department, (c) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (d) when required by law; (D) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by these provisions.

4. In the event the Department deems it desirable or necessary, in determining whether particular records are required to be disclosed under the Freedom of Information Act, disclosure may be made to the Department of Justice for the purpose of obtaining its advice.

5. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

6. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of the individual.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Data may be stored in file folders, magnetic tapes or discs, punched cards, or bound notebooks. Stored data may include textual, photographic, X-ray, or other material.

RETRIEVABILITY:

Information will be retrieved by personal identifiers such as name, code number and/or Social Security number, when this is supplied on a voluntary basis.

SAFEGUARDS:

Measures to prevent unauthorized disclosures are implemented as appropriate for each location and for the particular records maintained in each project. Each site implements personnel, physical and procedural safeguards such as the following:

1. Authorized Users: Access will be limited to principal investigators, collaborating researchers and necessary support staff.

2. Physical Safeguards: Hard copy data will be maintained in locked file cabinets. Information stored in computer systems will be accessible only through proper sequencing of signal commands and access codes specifically assigned to the Project Officer or contractor.

3. Procedural Safeguards: Access to the information will be controlled directly by the Project Officer or his or her representative at remote locations, and by the system manager at NIA locations. Contractors and collaborating researchers will be notified that they are subject to the provisions of the Privacy Act, and will be required to make formal agreements to comply with these provisions.

The particular safeguards implemented in each project are developed in accordance with Chapter 45–13 and supplementing Chapter PHS hf: 45–13 of the HHS General Administration Manual and Part 6, ADP Systems Security, of the HHS Information Resources Management Manual, and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual, Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 3000–G–3, which allows records to be kept as long as they are useful in scientific research. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER AND ADDRESS:

Associate Director, Epidemiology, Demography and Biometry Program, National Institute on Aging, Gateway Building, Suite 3C321, 7201 Wisconsin Avenue, Bethesda, MD 20892.

NOTIFICATION PROCEDURE:

To determine if a record exists, write to the System Manager at the address below and provide the following information in writing:

1. Full name at time of participation in the study,
2. Date of birth,
3. Home address at the time of study,
4. The facility where the examination was given or where information was collected,
5. Approximate date or dates of participation,
6. Name of study, if known,
7. Current name, address and telephone number.

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

An individual who requests notification of or access to a medical or dental record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

RECORD ACCESS PROCEDURE:

Contact the system manager at the above address and provide the same information as outlined under the notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Contact the System Manager at the above address. The contestor must reasonably identify the record, specify in writing the information being contested, and state the corrective action sought and the reasons for the correction. The right to contest records is limited to information which is incomplete, irrelevant, incorrect or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Information will be obtained directly from individual participants and from medical and clinical research observations, or indirectly from existing source documents such as disease registries.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09-25-0148

SYSTEM NAME:

Contracted and Contract-Related Research: Records of Subjects in Clinical, Epidemiological and Biomedical Studies of the National Institute of Neurological Disorders and Stroke and the National Institute on Deafness and Other Communication Disorders, HHS/NIH/NINDS and HHS/NIH/NIDCD.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

At National Institutes of Health facilities in Bethesda, Maryland, and at hospitals, medical schools, universities, research institutions, commercial organizations, state agencies, and collaborating Federal agencies. Inactive records may be retired to Federal Records Centers. A list of locations is available upon request from the respective System Managers of the subsystems included in this notice.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Patients with neurological diseases, communicative disorders, stroke, hearing loss, chemosensory deficits, and related diseases; normal, healthy volunteers who serve as controls for comparison with patients; relatives of patients; and other individuals whose characteristics or conditions are suited for possible connections with the occurrence of the diseases and disorders under investigations. Subject individuals include both adults and children.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system consists of a variety of clinical, biomedical, and epidemiological information resulting from or contained in direct observations, medical records and other histories, vital statistics reports, records on biological specimens (e.g., blood, urine, etc.), personal interviews, questionnaires, progress reports, correspondence, or research findings.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Sections 241, Research and Investigation, and 289a, Establishment of Institutes, of the Public Health Service Act (42 U.S.C. 301, 431).

PURPOSE OF THE SYSTEM:

This system will be used to support (1) contracted and contract-related epidemiological, clinical and biometric investigations into the causes, nature, outcome, therapy, prevention and cost of neurological and communicative disorders, hearing loss, chemosensory deficits, and stroke; (2) review and evaluation of the progress of these research projects, and identification and planning for improvements or for additional research.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure may be made to HHS contractors, grantees and collaborating researchers and their staff in order to accomplish the research purpose for which the records are collected. The recipients are required to protect such records from improper disclosure.

2. Disclosure may be made to organizations deemed qualified by the Secretary to carry out quality assessments, medical audits or utilization review.

3. A record may be disclosed for a research purpose, when the Department: (A) Has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained; (B) has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring; (C) has required the recipient to (1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except (a) in emergency circumstances affecting the health or safety of any individual, (b) for use in another research project, under these same conditions, and with written authorization of the Department, (c) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (d) when required by law; (D) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by these provisions.

4. In the event the Department deems it desirable or necessary, in determining

whether particular records are required to be disclosed under the Freedom of Information Act, disclosures may be made to the Department of Justice for the purpose of obtaining its advice.

5. The Department contemplates that it may contract with a private firm for the purpose of collating, analyzing, aggregating or otherwise refining records in this system. Relevant records will be disclosed to such a contractor. The contractor will be required to maintain Privacy Act safeguards with respect to such records.

6. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example in defending against a claim based upon an individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

7. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Data may be stored in file folders, computer-accessible forms (e.g. tapes or discs), punched cards, bound notebooks, microfilm, charts, graphs and X-rays.

RETRIEVABILITY:

Information is retrieved by name and/or patient identification number.

SAFEGUARDS:

1. Authorized Users: Access to or disclosure of information is limited to collaborating researchers, contractors and employees, and other authorized biomedical researchers who are involved in the conduct, support or review and evaluation of the research activities supported by this system.

2. Physical Safeguards: Data are kept in secured areas (e.g. rooms which are locked when not in regular use, buildings with controlled access). Data stored in computer-accessible form is accessed through the use of key words known only to principal investigators or authorized personnel; all other information is stored in locked files.

3. Procedural Safeguards: Contractors and collaborating or other researchers are required to comply with the provisions of the Privacy Act and with HHS Privacy Act regulations.

These and other appropriate safeguards are implemented in each project in accordance with Chapter 45–13, "Safeguarding Records Contained in Systems of Records," of the HHS General Administration Manual, supplementary Chapter PHS.hf: 45–13, and Part 6, "ADP Systems Security," of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual, Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 3000–G–3, which allows records to be kept as long as they are useful in scientific research. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGERS AND ADDRESSES:

NINDS and NIDCD research activities are divided, functionally and administratively. In effect, there are six subsystems within this single umbrella system. NINDS has five programs and NIDCD one. System Managers have been designated for each subsystem as follows:

Director, Division of Communication Sciences and Disorders, NIDCD, NIH, Executive Plaza South, Room 400B, 620 Executive Boulevard, Rockville, MD 20852.

and

Director, Division of Fundamental Neurosciences, NINDS NIH, Federal Building, Room 916, 7550 Wisconsin Avenue, Bethesda, MD 20892.

and

Director, Division of Convulsive, Developmental and Neuromuscular Disorders, NINDS, NIH, Federal Building, Room 816, 7550 Wisconsin Avenue, Bethesda, MD 20892.

and

Director, Division of Demyelinating Atrophic, and Dementing Disorders, NINDS, NIH, Federal Building, Room 810, 7550 Wisconsin Avenue, Bethesda, MD 20892.

and

Director, Division of Stroke and Trauma, NINDS, NIH, Federal Building, Room 8A08, 7550 Wisconsin Avenue, Bethesda, MD 20892.

and

Director, Division of Intramural Research, NIH, Building 10, Room 5N14, 9000 Rockville Pike, Bethesda, MD 20892.

NOTIFICATION PROCEDURE:

To determine if a record exists, write to:

NINDS Privacy Act Coordinator, Federal Building, Room 816, 7550 Wisconsin Avenue, Bethesda, MD 20892.

or

NIDCD Privacy Act Coordinator, Building 31, Room 3C02, 9000 Rockville Pike, Bethesda, MD 20892.

and provide the following information:

1. System name,
2. Complete name and home address at the time of the study,
3. Birth date,
4. Facility conducting the study,
5. Disease type (if known),
6. Approximate dates of enrollment in the research study.

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

Individuals seeking notification of or access to medical records should designate a representative (including address) who may be a physician, other health professional, or other responsible individual, who would be willing to review the record and inform the subject individual of its contents, at the representative's discretion.

A parent or guardian who requests notification of, or access to, a child's or incompetent person's medical record shall designate a family physician or other health professional (other than a family member) of whom the record, if any, will be sent. The parent or guardian must verify relationship to the child or incompetent person as well as his or her own identity.

RECORD ACCESS PROCEDURE:

Same as notifications procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Write to the system manager and reasonably identify the record, specify the information being contested and state the corrective action sought and the reasons for the correction. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Information in these records is obtained directly from individual participants, and from physicians, research investigators and other collaborating persons, and from medical records and clinical research observations at hospitals, HHS agencies, universities, medical schools, research institutions, commercial institutions, state agencies, and collaborating Federal agencies.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09-25-0151

SYSTEM NAME:

Administration: Public Health Service ALERT Records Concerning Individuals Under Investigation for Possible Misconduct in Science or Subject to Sanctions for Such Misconduct, HHS/PHS/NIH.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Office of Science Integrity National Institutes of Health (NIH) Building 31 Room B1C39 9000 Rockville Pike Bethesda, MD 20892.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Subjects may include (1) researchers currently or formerly employed by the Federal Government; (2) individuals being considered for appointment to Public Health Service (PHS) advisory committees; (3) investigators on research grants, fellowships, cooperative agreements, or contracts awarded by any PHS agency, ("Investigators" may include principal investigators, co-investigators, program directors, trainees, recipients of career awards or fellowships, or other individuals who conduct or are responsible for research or research training funded by PHS.); (4) research investigators, such as guest workers, not employed by PHS but who conduct research in PHS facilities or are closely associated with research conducted by PHS; (5) other individuals, such as subgrantees, subcontractors or assistants on research or research training grants, contracts or cooperative agreements, who by training, experience, occupation or other qualifications are potential candidates for research or research training grants, contracts, cooperative agreements or other benefits.

Such individuals would be subjects of records in this system if they fall within either of the following two categories:

(1) Subjects of formal investigations for scientific misconduct or serious misappropriation of Federal research funds, if the PHS Agency-level/Staff Office Misconduct Policy Officer has determined that the alleged misconduct is serious enough, or that the investigation has produced sufficient information, to warrant attention when a PHS agency considers awarding research or research training funds or other benefits to such individuals.

(2) Subjects of sanctions imposed as a result of determinations that scientific misconduct or serious misappropriation of Federal research funds has occurred. Such sanctions include (a) actions affecting eligibility for research and training awards, such as special conditions for receipt of an award, suspension or termination of an award, or debarment of an individual; (b) actions affecting eligibility for appointment to a committee which advises PHS; (c) special restrictions on regulated research, such as disqualification from eligibility to use investigational drugs or special conditions for protection of human research subjects; and (d) termination of employment or other disciplinary action against an employee of PHS.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system contains records relating to investigations or findings of misconduct in science and to actions that PHS has taken in connection with such investigations or findings. Misconduct in science is defined as (1) the serious deviation, such as fabrication, falsification, or plagiarism, from accepted practices in proposing, conducting and reporting the results of research; or (2) the material failure to comply with Federal requirements affecting specific aspects of the conduct of research, e.g., the protection of human subjects and the welfare of laboratory animals.

In addition to records relating to misconduct in science, the system includes records relating to investigations or findings of serious misappropriation of Federal research funds—e.g., diversion of such funds to personal use. It does not include records documenting normal business transactions between a PHS agency and an awardee institution, except to the extent that such records are directly relevant to consideration of the fitness of an individual to receive a PHS award or other benefit.

The system consists of two subsystems which contain the following types of records:

(1) Records on pending or ongoing investigations identifying the alleged misconduct; the individual and/or institution under investigation; any present, past or pending research, and/or research training awards; PHS agencies or offices involved, and the organization responsible for the investigation.

(2) Records summarizing sanctions imposed because of a finding of misconduct, which adversely affect the individual's eligibility for research or research training awards or other benefits for a specified period of time.

Either subsystem may contain responses from subject individuals.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Authority for this system comes from the legislation which authorizes PHS to make awards for biomedical research and research training, and from PHS's concomitant responsibility to assure both that funds disbursed under awards are spent for authorized purposes and that recipients of such funds conform to all appropriate laws and regulations. (Public Health Service Act: 42 U.S.C. 241, 242b, 242c, 242l, 242m, 247c, 281–289h, 290aa–9, 290bb, 290bb–1, 290cc, 300a–2 300b–1–b–3, 300c–12, 300z–7, as these provisions relate to awards for biomedical research and research training; Occupational Safety and Health Act: 29 U.S.C. 669).

PURPOSE OF THE SYSTEM:

This system of records enables PHS agencies to discharge effectively their responsibilities in the award and administration of research and training grants, cooperative agreements and contracts, while protecting the privacy and other rights of individuals under investigation or sanction for scientific misconduct or misappropriation of funds. The ALERT system is used to collect, control and disseminate to PHS agency officials on a need-to-know basis

information that an individual (1) is under investigation for possible misconduct in science or misappropriation of funds, or a decision has been made to undertake such an investigation; or (2) has been subjected to a sanction at the conclusion of an investigation for misconduct or misappropriation of funds.

Specifically,

(1) PHS records the existence of such sanctions in the system so that PHS agencies can track and implement the sanctions, for example by refusing to accept an application or proposal from a debarred person. In addition, PHS informs members of technical merit review groups of actions taken if the disclosure bears directly on the scientific merit of an application or proposal under consideration or the fiscal integrity of the investigator or applicant, or if necessary to ensure an unbiased review by providing an accurate account of the case, for example, when information concerning the conduct investigated has been disclosed by other sources, such as the press or other communications media. PHS does not use this system to make decisions on imposition of sanctions.

(2) When investigative findings fail to confirm an instance of misconduct or show that any misconduct was not of sufficient importance to warrant imposing sanctions, leading to a decision not to impose any sanctions, (a) the individual's name is removed from the ALERT system of records and the individual is notified in writing; (b) responsible PHS agency officials are notified of the outcome; (c) if any interim administrative sanctions had been imposed, they are lifted; and (d) if a competing application or proposal from the individual is pending or anticipated in the near future, the Misconduct Policy Officer of the relevant agency consults with officials responsible for review of the application or proposal to identify and resolve any concerns that might affect the objectivity of the review. For example, technical merit review groups would be informed of the outcome of the investigation if there were reason to believe that reviewers had received incomplete or misleading information about the case.

(3) PHS agencies use ALERT system records on pending or ongoing investigations to make informed decisions on appropriate actions regarding awards of research, research training and related activities or other benefits to individuals under investigation as follows: (a) PHS agency officials responsible for the award of research funds, in consultation with the PHS agency-level Misconduct Policy Officer, weigh information on investigations in deciding whether to take interim administrative action, such as delaying, restricting or denying award of research funds. Any interim action is taken with a view towards protecting the rights of all parties involved and minimizing disruption to an ongoing project, the awardee institution, and the activities of those involved in the project. (b) To obtain independent advice on appropriate actions with respect to potential competing awards to individuals or organizations under investigation, these officials or their designees inform the members of the appropriate National Advisory Council or Board, advisory bodies legally established to advise PHS on funding of research projects, of the existence and status of an investigation. Such disclosure is made in closed session when the Council or Board is considering the funding of research by the individual or institution. To avoid influencing Technical Reviews, PHS will not inform members of scientific review groups about instances of possible misconduct or ongoing investigations. However, if a given case has received such extensive publicity that review of an application or proposal may be compromised, the responsible PHS agency official may defer the review or inform the reviewers of the status of PHS's activities with respect to the possible misconduct.

(4) The PHS Committee on Misconduct in Science, and individual PHS Agency/Staff Office Misconduct Policy Officers, review ALERT records in order to inform appropriate officials within their organizations who are responsible for deciding on the actions described in other items of this section.

(5) PHS Committee Management Officers may review records in the system concerning candidates for appointment to advisory committees in order to make informed decisions about making, delaying or denying appointments.

(6) Upon request, the system manager may disclose information to PHS agency officials who are considering hiring a subject individual.

(7) When a research activity within PHS (i.e., intramural research activity) is the subject of an investigation by a PHS regulatory agency, information on that investigation in this system may be communicated to the PHS intramural officials responsible for the research activity.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. PHS may notify responsible officials of awardee institutions or organizations when, in connection with an investigation or finding of misconduct by an individual employed by or affiliated with the institution or organization, a PHS agency takes an action affecting research and research training awards to the institution or organization. Information disclosed will be limited to the name of the subject individual, description of the action and the reasons for it.

2. Information may be disclosed to qualified experts not within the definition of Department employees as prescribed in Department Regulations to the extent the information is pertinent to the review of applications by those experts.

3. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

4. Disclosure may be made from this system of records to the Department of Justice, or to a court or other tribunal, when (a) HHS, or any component thereof; or (b) HHS employee in his or her individual capacity or (c) any HHS employee in his or her individual capacity where the Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the employee; or (d) the United States or any agency thereof where HHS determines that the litigation is likely to affect HHS or any of its components is a party to litigation or has an interest in such litigation, and HHS determines that the use of such records by the Department of Justice, court or other tribunal is relevant and necessary to the litigation and would help in the effective representation of the governmental party, provided, however, that in each case, HHS determines that such disclosure is compatible with the purpose for which the records were collected.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored in file folders.

RETRIEVABILITY:

Records are retrieved by name of the individual under investigation or subject to sanction.

SAFEGUARDS:

1. Authorized Users: Records are available only to the system manager, PHS Agency-level/Staff Office Misconduct Policy Officers, the Deputy Director for Extramural Research and Training, NIH, and other responsible PHS agency officials considering the award of funds for research, research training or related activities or other benefits to a subject individual or institution, the appointment of a subject individual to an advisory committee, the hiring of a subject individual, or the management of a PHS agency research activity under investigation. Any disclosure to other individuals must be authorized by the system manager.

2. Procedural Safeguards: Access to records is strictly controlled by the system manager and the officials specified under "Authorized Users." Individuals who receive disclosures from this system are informed that the information is confidential. They are instructed to address all questions and inquiries from any party either to the system manager or to the appropriate Misconduct Policy Officer for reply. Disclosures to Boards, Councils or review groups are made in sessions which are closed to the public. In addition, PHS staff and others not directly responsible for a potential award may be barred when a Board or Council considers an ALERT case, if they would not have been informed about the case otherwise. Only the PHS Committee on Misconduct in Science or individual PHS agency-level Misconduct Policy Officers, acting on the advice of the system manager, may authorize additions, alterations or deletion of records in this system.

3. Physical Safeguards: Records are kept in locked file cabinets in offices which are locked when not attended. Special measures, commensurate with the sensitivity of the records, are taken to prevent unauthorized copying or disclosure of records.

These practices are in compliance with the standards of chapter 45–13 of the HHS General Administration Manual and supplementary chapter PHS hf: 45–13.

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 4000–E–3, which allows records on an investigation in progress to be retained until the investigation is completed. If the investigation results in a determination that no misconduct occurred, or that any misconduct was not significant enough to warrant official sanction, the record relating to that investigation is destroyed. If an investigation results in official sanction, a record of such sanction is maintained for the duration of the sanction and is then destroyed. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER AND ADDRESS:

Deputy Director, Office of Science Integrity, National Institutes of Health, Building 31, Room B1C39, 9000 Rockville Pike, Bethesda, MD 20892.

NOTIFICATION PROCEDURE:

Individuals are routinely notified in writing when they become the subject of a record in this system, unless a law enforcement agency has instructed PHS not to do so. Subject individuals are also informed routinely when their records are deleted from the system. Individuals may request notification by writing to the system manager at the address above; provide your full name and state that the inquiry concerns Privacy Act system of records number 09–25–0151. The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a fine of not more than five thousand dollars.

RECORD ACCESS PROCEDURE:

Individuals may write to the system manager at the address above and provide the same information as required for notification. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Write to the system manager and reasonably identify the record and the information being contested; and state your reasons for requesting the change, along with supporting information to show that the record is untimely, incomplete, irrelevant or inaccurate. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Information in these records is obtained from subject individuals, awardee institutions or organizations, PHS agencies and organizations responsible for investigations.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09–25–0153

SYSTEM NAME:

Biomedical Research: Records of Subjects in Biomedical and Behavioral Studies of Child Health and Human Development, HHS/NIH/NICHD.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Records included in this system are located in hospitals and clinics, research centers, educational institutions, commercial organizations, local and State agencies, and other Executive Branch agencies of the Federal Government under contract to the National Institute of Child Health and Human Development (NICHD), and in NICHD facilities in Bethesda, Maryland. Inactive records may be stored at Federal Records Centers. A list of specific locations and contractors is available upon request from the System Manager, whose address is listed below.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Participants in these studies include adults and children (a) who are presently or have been treated by the NICHD, (b) whose physical, genetic, social, economic, environmental, behavioral or nutritional conditions or habits are being studied by the NICHD, or (c) normal volunteers who have agreed to provide control data for purposes of comparison.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system consists of a variety of clinical, medical, and statistical information collected in biomedical and behavioral research studies, such as medical histories, vital statistics, personal interviews, questionnaires, current addresses of study participants, radiographs, records on biological specimens, study models, and correspondence from or about participants in these studies.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Section 301, Research and Investigation, and section 441, National Institute of Child Health and Human Development, of the Public Health Service Act as amended (42 U.S.C. sections 241, 298d).

PURPOSE(S) OF THE SYSTEM:

This system is used: (1) For program review, evaluation, planning, and administrative management for research on child health and human development; (2) to monitor the incidence, prevalence or development of the disease, condition, behavior, or health status under investigation; (3) to determine the relation of various factors (e.g., social, economic, environmental, physical, and medical) to the occurrence of the disease, condition, development, behavior, or health status under investigation; (4) to identify abnormal disease, condition, or health status and inform the Centers for Disease Control (CDC) or the Food and Drug Administration (FDA) of the existence of such conditions. CDC uses this information in fulfilling its congressionally mandated responsibility for the monitoring of disease and prevention of epidemics. FDA uses this information in carrying out its congressional mandate for controlling certain potentially harmful products.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure may be made to HHS contractors, grantees and collaborating researchers and their staff for the purpose of analyzing data and preparing scientific reports and articles in order to accomplish the research purpose for which the records are collected. The recipients are required to comply with the requirements of the Privacy Act with respect to such records.

2. Disclosure may be made to organizations deemed qualified by the Secretary to carry out quality assessment, medical audits or utilization review.

3. The Department contemplates that it may contract with a private firm for the purpose of collating, analyzing, aggregating or otherwise refining records in this system. Relevant records will be disclosed to such a contractor. The contractor will be required to comply with the requirements of the Privacy Act with respect to such records.

4. Certain diseases and conditions, including infectious diseases, may be reported to appropriate representatives of State or Federal Government as required by State or Federal law.

5. A record may be disclosed for a research purpose, when the Department: (A) Has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained; (B) has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring; (C) has required the recipient to (1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except (a) in emergency circumstances affecting the health or safety of any individual, (b) for use in another research project, under these same conditions, and with written authorization of the Department, (c) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (d) when required by law; (D) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by these provisions.

6. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

7. In the event of litigation where the defendant is: (a) The Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example in defending against a claim based upon an individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Data may be stored in file folders, microfilm, magnetic tapes or disks, punched cards, or bound notebooks.

RETRIEVABILITY:

Information is retrieved by name and/or a participant identification number.

SAFEGUARDS:

Measures to prevent unauthorized disclosures are implemented as appropriate for each location and for the particular records maintained in each project. Each site implements personnel, physical and procedural safeguards such as the following:

1. Authorized Users: Employees who maintain records in this system are instructed to grant regular access only to contractor personnel; consultants to the contractor; the NICHD project officer; and NICHD employees whose duties require the use of such information. One time and special access to the data is controlled by the System Manager, the NICHD Project Officer, and the Contract and/or Project Director.

2. Physical Safeguards: Records are stored in locked files or secured areas. Computer terminals are in secured areas.

3. Procedural Safeguards: Names and other identifying particulars are deleted when data from original records is encoded for analysis. Encoded data is indexed by code numbers. Tables linking these code numbers with actual identifiers are maintained separately. Code numbers and identifiers are linked only if there is a specific need, such as alerting the volunteer subjects to any findings in the study that might affect their health. Data stored in computers is accessed through the use of passwords/keywords known only to the principal investigators or authorized personnel. These passwords/keywords are changed frequently.

The particular safeguards implemented in each project will be developed in accordance with Chapter 45–13, "Safeguarding Records Contained in Systems of Records," of the HHS General Administration Manual, supplementary Chapter PHS hf: 45–13; Part 6, "ADP Systems Security," of the HHS ADP Systems Manual, and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 3000–G–3, which allows records to be kept as long as they are useful in scientific research. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER AND ADDRESS:

Chief, Contracts Management Branch, NICHD, Executive Plaza North, Room 610H, 6130 Executive Blvd., North Bethesda, MD 20892.

NOTIFICATION PROCEDURE:

To determine if a record exists, write to: NICHD Privacy Act Coordinator, Building 31, Room 2A–17, 9000 Rockville Pike, Bethesda, MD 20892, and provide the following information in writing:

1. Full name and address at time of participation in the study.
2. Name or description of the study.
3. Location and approximate dates of participation.

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

An individual who requests notification of, or access to, a medical record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

A parent or guardian who requests notification of, or access to, the medical record of a child or incompetent person shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify his or her relationship to the child or incompetent person as well as his or her own identity.

RECORD ACCESS PROCEDURES:

Same as notification procedure above. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURES:

Write to the official specified under notification procedures above, and reasonably identify the record and specify the information being contested, the corrective action sought, and your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely or irrelevant. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Information contained in these records is obtained directly from individual participants, medical and clinical research observations, and other federal agencies.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09–25–0156

SYSTEM NAME:

Records of Participants in Programs and Respondents in Surveys Used to Evaluate Programs of the National Institutes of Health, HHS/NIH/OD.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

This system of records is an umbrella system comprising separate sets of records located either in the organizations responsible for conducting evaluations or at the sites of programs or activities under evaluation. Locations include National Institutes of Health (NIH) facilities in Bethesda, Maryland, or facilities of contractors of the NIH. Write to the appropriate System Manager below for a list of current locations.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals covered by this system are those who provide information or opinions that are useful in evaluating programs or activities of the NIH, other persons who have participated in or benefitted from NIH programs or activities; or other persons included in evaluation studies for purposes of comparison. Such individuals may include (1) participants in research studies; (2) applicants for and recipients of grants, fellowships, traineeships or other awards; (3) employees, experts and consultants; (4) members of advisory committees; (5) other researchers, health care professionals, or individuals who have or are at risk of developing diseases or conditions studied by NIH; (6) persons who provide feedback about the value or usefulness of information they receive about NIH programs, activities or research results; (7) persons who have received Doctorate level degrees from U.S. institutions; (8) persons who have worked or studied at U.S. institutions that receive(d) institutional support from NIH.

CATEGORIES OF RECORDS IN THE SYSTEM:

This umbrella system of records covers a varying number of separate sets of records used in different evaluation studies. The categories of records in each set depend on the type of program being evaluated and the specific purpose of the evaluation. In general, the records contain two types of information: (1) Information identifying subject individuals, and (2) information which enables NIH to evaluate its programs and services.

(1) Identifying information usually consists of a name and address, but it might also include a patient identification number, grant number, Social Security Number, or other identifying number as appropriate to the particular group included in an evaluation study.

(2) Information used for evaluation varies according to the program evaluated. Categories of evaluative information include personal data and medical data on participants in clinical and research programs; personal data, publications, professional achievements and career history of researchers; and opinions and other information received directly from individuals in evaluation surveys and studies of NIH programs.

The system does not include any master list, index or other central means of identifying all individuals whose records are included in the various sets of records covered by the system.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Authority for this system comes from the authorities regarding the establishment of the National Institutes of Health, its general authority to conduct and fund research and to provide training assistance, and its general authority to maintain records in connection with these and its other functions (42 U.S.C. 203, 241, 289l–1 and 44 U.S.C. 3101).

PURPOSE OF THE SYSTEM:

This system supports evaluation of the policies, programs, organization, methods, materials, activities or services used by NIH in fulfilling its legislated mandate for (1) conduct and support of biomedical research into the causes, prevention and cure of diseases; (2)

support for training of research investigators; (3) communication of biomedical information.

This system is not used to make any determination affecting the rights, benefits or privileges of any individual.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure may be made to HHS contractors and collaborating researchers, organizations, and State and local officials for the purpose of conducting evaluation studies or collecting, aggregating, processing or analyzing records used in evaluation studies. The recipients are required to protect the confidentiality of such records.

2. Disclosure may be made to organizations deemed qualified by the Secretary to carry out quality assessments, medical audits or utilization review.

3. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

4. The Department may disclose information from this system of records to the Department of Justice, to court or other tribunal, or to another party before such tribunal, when (a) HHS, or any component thereof; or (b) any HHS employee in his or her official capacity; or (c) any HHS employee in his or her individual capacity where the Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the employee; or (d) the United States or any agency thereof where HHS or any of its components, is a party to litigation or has an interest in such litigation, and HHS determines that the use of such records by the Department of Justice, the tribunal, or the other party is relevant and necessary to the litigation and would help in the effective representation of the governmental party, provided, however, that in each case, HHS determines that such disclosure is compatible with the purpose for which the records were collected.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Data may be stored in file folders, bound notebooks, or computer-accessible media (e.g., magnetic tapes or discs).

RETRIEVABILITY:

Information is retrieved by name and/or participant identification number within each evaluation study. There is no central collection of records in this system, and no central means of identifying individuals whose records are included in the separate sets of records that are maintained for particular evaluation studies.

SAFEGUARDS:

A variety of safeguards are implemented for the various sets of records in this system according to the sensitivity of the data each set contains. Information already in the public domain, such as titles and dates of publications, is not restricted. However, sensitive information, such as personal or medical history or individually identified opinions, is protected according to its level of sensitivity. Records derived from other systems of records will be safeguarded at a level at least as stringent as that required in the original systems. Minimal safeguards for the protection of information which is not available to the general public include the following:

1. Authorized Users: Regular access to information in a given set of records is limited to NIH or to contractor employees who are conducting, reviewing or contributing to a specific evaluation study. Other access is granted only on a case-by-case basis, consistent with the restrictions required by the Privacy Act (e.g., when disclosure is required by the Freedom of Information Act), as authorized by the system manager or designated responsible official.

2. Physical Safeguards: Records are stored in closed or locked containers, in areas which are not accessible to unauthorized users, and in facilities which are locked when not in use. Records collected in each evaluation project are maintained separately from those of other projects. Sensitive records are not left exposed to unauthorized persons at any time. Sensitive data in machine-readable form may be encrypted.

3. Procedural Safeguards: Access to records is controlled by responsible employees and is granted only to authorized individuals whose identities are properly verified. Data stored in mainframe computers is accessed only through the use of keywords known only to authorized personnel. When personal computers are used, magnetic media (e.g. diskettes) are protected as under Physical Safeguards. When data is stored within a personal computer (i.e., on a "hard disk"), the machine itself is treated as though it were a record, or records, under Physical Safeguards. Contracts for operation of this system of records require protection of the records in accordance with these safeguards; NIH project and contracting officers monitor contractor compliance. These practices are in compliance with the standards of Chapter 45–13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45–13, and Part 6, "ADP Systems Security," of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 1100–C–2. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGERS AND ADDRESSES:

See Appendix 1.

Policy coordination for this system is provided by: Director, Division of Planning and Evaluation, Office of Science Policy and Legislation, National Institutes of Health, Building 31, Room 4B25, 9000 Rockville Pike, Bethesda, MD 20892.

NOTIFICATION PROCEDURE:

To determine if a record exists, write to the official of the organization responsible for the evaluation, as listed in Appendix 2. If you are not certain which component of NIH was responsible for the evaluation study, or if you believe there are records about you in several components of NIH, write to: NIH Privacy Act Coordinator Building 31, Room 3B07 9000 Rockville Pike Bethesda, MD 20892.

Requesters must provide the following information:

1. Full name, and name(s) used while studying or employed;

2. Name and location of the evaluation study or other NIH program in which the requester participated or the institution at which the requester was a student or employee, if applicable;

3. Approximate dates of participation, matriculation or employment, if applicable.

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for

acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

An individual who requests notification of or access to a medical record shall, at the time the request is made, designate in writing, a responsible representative, who may be a physician, other health professional, or other responsible individual, who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

A parent or guardian who requests notification of, or access to, a child's or incompetent person's medical record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the child or incompetent person as well as his or her own identity.

RECORD ACCESS PROCEDURES:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURES:

Write to the official specified under notification procedures above, and reasonably identify the record and specify the information being contested, the corrective action sought, and your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely or irrelevant. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Information contained in these records is obtained directly from individual participants; from systems of records 09–25–0036, "Grants: IMPAC (Grants/Contract Information), HHS/NIH/DRG;" 09–25–0112, "Grants: Research, Research Training, Fellowship and Construction Applications and Awards, HHS/NIH/OD"; NSF–6, "Doctorate Record File", NSF–43, "Doctorate Work History File" (previously entitled "NSF–43, "Roster and Survey of Doctorate Holders in The United States" and other records maintained by the operating programs of NIH; the National Academy of Sciences, professional associations such as the AAMC and ADA, and other contractors; grantees or collaborating researchers; or publicly available sources such as bibliographies.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT: NONE.

Appendix 1—System managers

National Institutes of Health, Office of the Director, Director, Division of Planning and Evaluation Office of Science Policy and Legislation Building 31, Room 4B25 9000 Rockville Pike Bethesda, MD 20892.

National Institutes of Health, Office of the Director, Director, Division of Personnel Management Building 1, Room B1–60 9000 Rockville Pike Bethesda, MD 20892.

National Heart, Lung, and Blood Institute (NHLBI) Director, Office of Program Planning & Evaluation Building 31, Room 5A03 Bethesda, MD 20892.

National Library of Medicine (NLM) Assistant Director for Planning and Evaluation Building 38, Room 2S18 Bethesda, MD 20894.

National Eye Institute (NEI) Associate Director, Office of Science Policy and Legislation Building 31, Room 6A27 Bethesda, MD 20892.

National Cancer Institute (NCI) Public Health Educator, OCC, NCI National Institutes of Health Building 31, Room 4B43 Bethesda, MD 20892.

National Institute on Aging (NIA), Chief, Office of Planning, Analysis, Technical Information and Evaluation, Federal Building, Room 6A09, 7550 Wisconsin Avenue, Bethesda, MD 20892.

National Institute of Allergy and Infectious Diseases (NIAID), Chief, Evaluation and Reporting Section, Policy Analysis and Legislation Branch, Office of Administration Management, Building 31, Room 7A52, Bethesda, MD 20892.

National Institute of Child Health and Human Development (NICHD), Chief, Office of Science Policy and Analysis, Building 31, Room 2A10, Bethesda, MD 20892.

National Institute on Deafness and Other Communication Disorders, Chief, Program Planning and Health Reports Branch, Building 31, Room 3C35, 9000 Rockville Pike, Bethesda, MD 20892.

National Institute of Dental Research (NIDR), Chief, Office of Planning Evaluation, and Communications, Building 31, Room 2C36, Bethesda, MD 20892.

National Institute of Environmental Health Sciences (NIEHS) Program Analyst, Office of Program Planning and Evaluation, P.O. Box 12233, Research Triangle Park, N.C. 27709.

National Institute of General Medical Sciences (NIGMS), Chief, Office of Program Analysis, Westwood Building, Room 934, 5333 Westbard Avenue, Bethesda, MD 20892.

Fogarty International Center (FIC), National Institutes of Health, Assistant Director for Planning, Evaluation and Public Affairs, Building 31, Room B2C32, Bethesda, MD 20892.

Division of Research Grants (DRG), Assistant Director for Special Projects, Westwood Building, Room 457, 5333 Westbard Avenue, Bethesda, MD 20892.

National Center for Research Resources (NCRR), Evaluation Officer, Office of Science Policy, Westwood Building, Room 8A03, Bethesda, MD 20892.

National Center for Nursing Research (NCNR), Chief, Office of Planning, Analysis and Evaluation, Building 31, Room 5B13, Bethesda, MD 20892.

Appendix 2—Notification and Access Officials

NIH, Office of the Director, Associate Director for Science, Policy and Legislation, Building 1, Room 137, 9000 Rockville Pike, Bethesda, MD 20892.

National Institutes of Health, Office of the Director, Director, Division of Personnel Management, Building 1, Room B1–60, 9000 Rockville Pike, Bethesda, MD 20892.

National Heart, Lung, and Blood Institute (NHLBI), Privacy Act Coordinator, Building 31, Room 5A29, Bethesda, MD 20892.

National Library of Medicine (NLM), Assistant Director for Planning and Evaluation, Building 38, Room 2S18, Bethesda, MD 20894.

National Eye Institute (NEI), Executive Officer, Building 31, Room 6A25, Bethesda, MD 20892.

Fogarty International Center (FIC), National Institutes of Health, Assistant Director for Planning, Evaluation and Public Affairs, Building 31, Room B2C32, Bethesda, MD 20892.

Division of Research Grants (DRG), Assistant Director for Special Projects, Westwood Building, Room 457, 5333 Westbard Avenue, Bethesda, MD 20892.

National Center for Research Resources (NCRR), Evaluation Officer, Office of Science Policy, NIH, Westwood Building, Room 8A03, Bethesda, MD 20892.

National Cancer Institute, Privacy Act Coordinator, National Institutes of Health, Building 31, Room 10A30, Bethesda, MD 20892.

09–25–0161

SYSTEM NAME:

Administration: NIH Consultant File, HHS/NIH/DRG.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

This system of records is an umbrella system comprising separate sets of records located in each of the NIH organizational components or facilities of contractors of the NIH.

Division of Computer Research and Technology, Data Management Branch, Building 12A, Room 4041B, National Institutes of Health, Bethesda, Maryland 20892.

Write to the appropriate system manager listed in Appendix I for a list of current locations.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Consultants who provide the evaluation of extramural grants and cooperative agreement applications and

research contract proposals, including the NIH Reviewers' Reserve.

CATEGORIES OF RECORDS IN THE SYSTEM:

Names, addresses, resumes, curriculum vitae (C.V.s), areas of expertise, publications.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Section 301 of the Public Health Service Act, describing the general powers and duties of the Public Health Service relating to research and investigation, and Section 402 of the Public Health Service Act, describing the appointment and authority of the Director of the National Institutes of Health, (42 USC 241 and 282).

PURPOSE OF THE SYSTEM:

This umbrella system comprises separate sets of records located in each of the NIH organizational components or facilities of contractors of the NIH. These records are used: (1) To identify and select experts and consultants for program reviews and evaluations; and (2) To identify and select experts and consultants for the review of special grant and cooperative agreement applications and research contract proposals.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

2. Disclosure may be made to the Department of Justice or to a court or other tribunal from this system of records, when (a) HHS, or any component thereof; or (b) any HHS employee in his or her official capacity; or (c) any HHS employee; or (d) the United States or any agency thereof where HHS determines that the litigation is likely to affect HHS or any of its components, is a party to litigation or has an interest in such litigation, and HHS determines that the use of such records by the Department of Justice, court or other tribunal is relevant and necessary to the litigation and would help in the effective representation of the governmental party, provided, however, that in each case HHS determines that such disclosure is compatible with the purpose for which the records were collected.

3. Disclosure may be made to contractors to process or refine the records. Contracted services may include transcription, collation, computer input, and other records processing.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records may be stored in file folders and computer tapes and disks.

RETRIEVABILITY:

Records are retrieved by name, address, or expertise.

SAFEGUARDS:

1. Authorized Users: Data on computer files is accessed by keyword known only to authorized users who are NIH or contractor employees involved in managing a review or program advisory committee, conducting a review of extramural grant applications, cooperative agreement applications, or research contract proposals, performing an evaluation study or managing the consultant file. Access to information is thus limited to those with a need to know.

2. Physical Safeguards: Rooms where records are stored are locked when not in use. During regular business hours rooms are unlocked but are controlled by on-site personnel.

3. Procedural Safeguards: Names and other identifying particulars are deleted when data from original records are encoded for analysis. Data stored in computers is accessed through the use of keywords known only to authorized users.

This system of records will be protected according to the standards of Chapter 45–13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45–13, and Part 6, "ADP Systems Security," of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 1100–G. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER(S) AND ADDRESS:

The policy coordinator for this system is also the system manager listed for the Division of Research Grants.

Chief, Physiological Sciences Review Section, Referral and Review Branch, Division of Research Grants, Westwood Building, Room 203A, 5333 Westbard Avenue, Bethesda, Maryland 20892,

and

See Appendix I.

NOTIFICATION PROCEDURE:

To determine if a record exists, write to the appropriate system manager as listed in Appendix I.

The requestor must also verify his or her identity by providing either a notarization of the request or a written certification that the requestor is whom he or she claims to be. The request should include: (a) Full name, and (b) appropriate dates of participation.

RECORD ACCESS PROCEDURE:

Same as notification procedures. Requestors should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Contact the official under notification procedures above, reasonably identify the record, specify the information to be contested, and state the corrective action sought with supporting information. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Subject individual.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

Appendix I: System managers

Office of the Director (OD), Extramural Programs Management Officer, Building 1, Room 328, Bethesda, MD 20892.

National Center for Research Resources (NCRR), Director, Office of Review, Westwood Building, Room 10A14, Bethesda, MD 20892.

National Cancer Institute (NCI), Chief, Review Logistics Branch, Westwood Building, Room 850, Bethesda, MD 20892.

National Eye Institute (NEI), Review and Special Projects Officer, Building 31, Room 6A06, Bethesda, MD 20892.

National Heart, Lung, and Blood Institute (NHLBI), Associate Director for Review, Westwood Building, Room 557A, Bethesda, MD 20892.

National Institute on Aging (NIA), Chief, Scientific Review Office, Gateway Building, Suite 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892.

National Institute of Allergy and Infectious Diseases (NIAID), Deputy Director, Division of Extramural Activities, Control Data Bldg., Room 4C–03, 6003 Executive Blvd., Rockville, MD 20892.

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), Chief, Grants Review Branch, Westwood Building, Room 5A07, Bethesda, MD 20892.
National Institute of Child Health and Human Development (NICHD), Director, Division of Scientific Review, Executive Plaza North, Room 520, Bethesda, MD 20892.
National Institute on Deafness and Other Communication Disorders (NIDCD), Chief, Scientific Review Branch, Executive Plaza South, Room 400B, 620 Executive Boulevard, Rockville, MD 20852.
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), Chief, Review Branch, Westwood Building, Room 406, Bethesda, MD 20892.
National Institute of Dental Research (NIDR), Chief, Scientific Review Branch, Westwood Building, Room 519, Bethesda, MD 20892.
National Institute of Environmental Health Sciences (NIEHS), Deputy Director, Division of Extramural Research and Training, P.O. Box 12233, Research Triangle Park, NC 27709.
National Institute of General Medical Sciences (NIGMS), Chief, Office of Review Activities, Westwood Building, Room 9A18, Bethesda, MD 20892.
National Institute of Neurological Disorders and Stroke (NINDS), Chief, Scientific Review Branch, Federal Building, Room 9C10A, Bethesda, MD 20892.
National Center for Nursing Research (NCNR), Executive Secretary, NRRC and NACNR, Building 31, Room 5B19, Bethesda, MD 20892.
National Library of Medicine (NLM), Chief, Biomedical Information Support Branch, Building 38A, Room 5S522, Bethesda, MD 20894.
National Center for Human Genome Research (NCHGR), Chief, Office of Scientific Review, Building 38, Room 6N613, Bethesda, MD 20892.
Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA), Associate Director for Referral and Review, Parklawn Building, Room 13–103, Rockville, MD 20857.

09–25–0165

SYSTEM NAME:

National Institutes of Health Acquired Immune Deficiency Syndrome (AIDS) Research Loan Repayment Program, HHS/NIH/OD.

SECURITY CLASSIFICATION:

None

SYSTEM LOCATION:

Office of AIDS Research (OAR), National Institutes of Health, Building 31, Room 5C12, 9000 Rockville Pike, Bethesda, Maryland 20892.
Division of Computer Research and Technology (DCRT), National Institutes of Health, Building 12A, Room 4037, 9000 Rockville Pike, Bethesda, Maryland 20892.
Division of Financial Management (DFM), Operations Accounting Branch, National Institutes of Health, Building 31, Room B1B55, 9000 Rockville Pike, Bethesda, Maryland 20892.

Write to the System Manager at the address below for the address of any Federal Records Center where records from this system may be stored.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who have applied for, who have been approved to receive, who are receiving, and who have received funds under the NIH AIDS Research LRP; and individuals who are interested in participation in the NIH AIDS Research LRP.

CATEGORIES OF RECORDS IN THE SYSTEM:

Name, address, Social Security number; service pay-back obligations, standard school budgets, educational loan data including deferment and repayment/delinquent/default status information; employment data; professional and credentialing history of licensed health professionals including schools of attendance; personal, professional, and demographic background information; employment status verification (which includes certifications and verifications of continuing participation in AIDS research); Federal, State and local tax information, including copies of tax returns.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Section 487A (42 USC 288–1) of the PHS Act, as amended, directing the NIH to establish and implement a program of educational loan repayment for qualified health professionals who agree to conduct, as employees of NIH, AIDS research. The provisions of section 338B of the PHS Act (42 USC 2541–1), as amended, governing the NHSC loan repayment program, are incorporated except as inconsistent. The Internal Revenue Code at 26 USC 6109 requires the provision of the SSN for the receipt of loan repayment funds under the NIH AIDS Research LRP.

PURPOSE(S) OF THE SYSTEM:

(1) To identify and select applicants for the NIH AIDS Research LRP.

(2) To monitor loan repayment activities, such as payment tracking, deferment of service obligation, and default.

(3) To assist NIH officials in the collection of overdue debts owed under the NIH AIDS Research LRP. Records may be transferred to system No. 09–15–0045, "Health Resources and Services Administration Loan Repayment/Debt Management Records System, HHS/HRSA/OA," for debt collection purposes when NIH officials are unable to collect overdue debts owed under the NIH AIDS Research LRP.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USE:

1. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

2. Disclosure may be made to the Department of Justice or to a court or other tribunal from this system of records, when (a) HHS, or any component thereof; or (b) any HHS employee in his or her official capacity; or (c) any HHS employee in his or her individual capacity where the Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the employee; or (d) the United States or any agency thereof where HHS determines that the litigation is likely to affect HHS or any of its components, is a party to litigation or has an interest in such litigation, and HHS determines that the use of such records by the Department of Justice, court or other tribunal is relevant and necessary to the litigation and would help in the effective representation of the governmental party, provided, however, that in each case HHS determines that such disclosure is compatible with the purpose for which the records were collected.

3. In the event that a system of records maintained by this agency to carry out its functions indicates a violation or potential violation of law, whether civil, criminal, or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule or order issued pursuant thereto, the relevant records in the system of records may be referred to the appropriate agency, whether Federal, State, or local, charged with enforcing or implementing the statute or rule, regulation or order issued pursuant thereto.

4. NIH may disclose records to Department contractors and subcontractors for the purpose of collecting, compiling, aggregating, analyzing, or refining records in the system. Contractors maintain, and are also required to ensure that subcontractors maintain, Privacy Act safeguards with respect to such records.

5. NIH may disclose information from this system of records to private parties such as present and former employers, references listed on applications and associated forms, other references and

educational institutions. The purpose of such disclosures is to evaluate an individual's professional accomplishments, performance, and educational background, and to determine if an applicant is suitable for participation in the NIH AIDS Research LRP.

6. NIH may disclose information from this system of records to a consumer reporting agency (credit bureau) to obtain a commercial credit report to assess and verify the ability of an individual to repay debts owed to the Federal Government. Disclosures are limited to the individual's name, address, Social Security number and other information necessary to identify him/her; the funding being sought or amount and status of the debt; and the program under which the applicant or claim is being processed.

7. NIH may disclose from this system of records a delinquent debtor's or a defaulting participant's name, address, Social Security number, and other information necessary to identify him/her; the amount, status, and history of the claim, and the agency or program under which the claim arose, as follows:

a. To another Federal agency so that agency can effect a salary offset for debts owed by Federal employees; if the claim arose under the Social Security Act, the employee must have agreed in writing to the salary offset.

b. To another Federal agency so that agency can effect an unauthorized administrative offset; i.e., withhold money, other than federal salaries, payable to or held on behalf of the individual.

c. To the Treasury Department, Internal Revenue Service (IRS), to request an individual's current mailing address to locate him/her for purposes of either collecting or compromising a debt, or to have a commercial credit report prepared.

8. NIH may disclose information from this system of records to another agency that has asked the Department to effect a salary or administrative offset to help collect a debt owed to the United States. Disclosure is limited to the individual's name, address, Social Security number, and other information necessary to identify the individual to information about the money payable to or held for the individual, and other information concerning the offset.

9. NIH may disclose to the Treasury Department, Internal Revenue Service (IRS), information about an individual applying for loan repayment under any loan repayment program authorized by the Public Health Service Act to find out whether the applicant has a delinquent tax account. This disclosure is for the sole purpose of determining the applicant's creditworthiness and is limited to the individual's name, address, Social Security number, other information necessary to identify him/her, and the program for which the information is being obtained.

10. NIH may report to the Treasury Department, Internal Revenue Service (IRS), as taxable income, the written-off amount of a debt owed by an individual to the Federal Government when a debt becomes partly or wholly uncollectible, either because the time period for collection under the statute of limitations has expired, or because the Government agrees with the individual to forgive or compromise the debt.

11. NIH may disclose to debt collection agents, other Federal agencies, and other third parties who are authorized to collect a Federal debt, information necessary to identify a delinquent debtor or a defaulting participant. Disclosure will be limited to the individual's name, address, Social Security number, and other information necessary to identify him/her; the amount, status, and history of the claim, and the agency or program under which the claim arose.

12. NIH may disclose information from this system of records to any third party that may have information about a delinquent debtor's or a defaulting participant's current address, such as a U.S. post office, a State motor vehicle administration, a professional organization, an alumni association, etc., for the purpose of obtaining the individual's current address. This disclosure will be strictly limited to information necessary to identify the individual, without any reference to the reason for the agency's need for obtaining the current address.

13. NIH may disclose information from this system of records to other Federal agencies that also provide loan repayment at the request of these Federal agencies in conjunction with a matching program conducted by these Federal agencies to detect or curtail fraud and abuse in Federal loan repayment programs, and to collect delinquent loans or benefit payments owed to the Federal Government.

14. NIH may disclose from this system of records to the Department of Treasury, Internal Revenue Service (IRS): (1) A delinquent debtor's or a defaulting participant's name, address, Social Security number, and other information necessary to identify the individual; (2) the amount of the debt; and (3) the program under which the debt arose, so that IRS can offset against the debt any income tax refunds which may be due to the individual.

15. NIH may disclose information provided by a lender to other Federal agencies, debt collection agents, and other third parties who are authorized to collect a Federal debt. The purpose of this disclosure is to identify an individual who is delinquent in loan or benefit payments owed to the Federal Government.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

Disclosures pursuant to 5 USC 552a(b)(12):

Disclosures may be made from this system to "consumer reporting agencies" as defined in the Fair Credit Reporting Act (15 USC 1681a(f)) or the Federal Claims Collection Act of 1966 (31 USC 3701(a)(3)). The purposes of these disclosures are: (1) To provide an incentive for debtors to repay delinquent Federal Government debts by making these debts part of their credit records, and (2) to enable NIH to improve the quality of loan repayment decisions by taking into account the financial reliability of applicants, including obtaining a commercial credit report to assess and verify the ability of an individual to repay debts owed to the Federal Government. Disclosure of records will be limited to the individual's name, Social Security number, and other information necessary to establish the identity of the individual, the amount, status, and history of the claim, and the agency or program under which the claim arose.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained in file folders, computer tape, discs, and file cards.

RETRIEVABILITY:

Records are retrieved by name, Social Security number, or other identifying numbers.

SAFEGUARDS:

1. Authorized Users: Data on computer files is accessed by keyword known only to authorized users who are NIH employees responsible for implementing the NIH AIDS Research LRP. Access to information is thus limited to those with a need to know.

2. Physical Safeguards: Rooms where records are stored are locked when not in use. During regular business hours rooms are unlocked but are controlled by on-site personnel. Security guards perform random checks on the physical security of the data.

3. Procedural and Technical Safeguards: A password is required to access the terminal and a data set name controls the release of data to only authorized users. All users of personal information in connection with the performance of their jobs (see Authorized Users, above) protect information from public view and from unauthorized personnel entering an unsupervised office.

These practices are in compliance with the standards of Chapter 45–13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45–13, the Department's Automated Information System Security Handbook, and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 2300–537–1. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER AND ADDRESS:

Director, NIH AIDS Research Loan Repayment Program, Office of AIDS Research, National Institutes of Health, Building 31, Room 5C12, 9000 Rockville Pike, Bethesda, Maryland 20892.

NOTIFICATION PROCEDURES:

To determine if a record exists, write to the System Manager listed above. The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be. The request should include: (a) Full name, and (b) appropriate dates of participation. The requester must also understand that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

RECORD ACCESS PROCEDURES:

Write to the System Manager specified above to attain access to records and provide the same information as is required under the Notification Procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request an accounting of disclosure of their records, if any.

CONTESTING RECORD PROCEDURES:

Contact the System Manager specified above and reasonably identify the record, specify the information to be contested, the corrective action sought, and your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely or irrelevant. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Subject individual; participating lending institutions; educational institutions attended; other Federal agencies; consumer reporting agencies/credit bureaus; and third parties that provide references concerning the subject individual.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09–25–0166

SYSTEM NAME:

Administration: Radiation Safety Information, HHS/NIH/ORS.

SECURITY CLASSIFICATION:

None

SYSTEM LOCATION:

Radiation Safety Branch, Division of Safety, Office of Research Services, NIH, Building 21, 9000 Rockville Pike, Bethesda, MD. 20892.

Write to System Manager at the address below for the address of the contractor or the Federal Records Center where records from this system may be stored.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

NIH employees using radioactive materials or radiation producing machinery, contractor employees who provide service to the Radiation Safety Branch and any other individuals who could potentially be exposed to radiation or radioactivity as a result of NIH operations and who, therefore, must be monitored in accordance with applicable regulations.

CATEGORIES OF RECORDS IN THE SYSTEM:

Names, birth dates, Social Security Numbers, titles, training data, exposure data, materials usage data, incident data.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 U.S.C. 241, regarding the general powers and duties of the Public Health Service relating to research and investigation; 5 U.S.C. 7902 regarding agency safety programs; and 42 U.S.C. 2201, regarding general duties of the Nuclear Regulatory Commission including the setting of standards to cover the possession and use of nuclear materials in order to protect health.

PURPOSE(S) OF THE SYSTEM:

1. To provide adequate administrative controls to assure compliance with NIH radiation safety policies and all appropriate regulations governing the use of radiation sources by NIH.

2. To assure legal compliance with requirements of Nuclear Regulatory Commission to maintain internal and external radiation exposure data and any radiation incident follow-up reports.

3. To monitor personnel exposures in order that they be maintained at the lowest levels reasonably achievable.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USE:

1. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

2. Disclosure may be made to the Department of Justice or to a court or other tribunal from this system of records, when (a) HHS, or any component thereof; or (b) any HHS employee in his or her official capacity; or (c) any HHS employee in his or her individual capacity where the Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the employee; or (d) the United States of any agency thereof where HHS determines that the litigation is likely to affect HHS or any of its components, is a party to litigation or has an interest in such litigation, and HHS determines that the use of such records by the Department of Justice, court or other tribunal is relevant and necessary to the litigation and would help in the effective representation of the governmental party, provided, however, that in each case HHS determines that such disclosure is compatible with the purpose for which the records were collected.

3. Disclosure may be made to contractors to provide services to the Radiation Safety Program, for the purpose of processing or refining the records. Contracted services may include transcription, collation,

computer input, and other records processing. The contractor shall be required to maintain Privacy Act safeguards with respect to such records.

4. Disclosure may be made to officials of the United States Nuclear Regulatory Commission which, by Federal regulation, licenses, inspects and enforces the regulations governing the use of radioactive materials.

5. Radiation exposure and/or training and experience history may be transferred to new employer.

6. A record may be disclosed for a research purpose, when the Department: (A) Has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained; (B) has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring; (C) has required the recipient to (1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except (a) in emergency circumstances affecting the health or safety of any individual, (b) for use in another research project, under these same conditions, and with written authorization of the Department, (c) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (d) when required by law; (D) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by these provisions.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM

STORAGE:

Records are maintained in file cabinets or in a computer database maintained by the Radiation Safety Branch (RSB). Records may be stored in file folders, magnetic tapes, magnetic disks, optical disks and/or other types of data storage devices.

RETRIEVABILITY:

Records are retrieved by name, unique RSB assigned identification number, or social security number.

SAFEGUARDS:

1. Authorized Users: Employees who maintain this system are instructed to grant regular access only to RSB staff, authorized contractor personnel, U.S. Nuclear Regulatory Commission Inspectors, Radiation Safety Committee Members, other appropriate NIH administrative and management personnel with a need to know. Access to information is thus limited to those with a need to know.

2. Physical Safeguards: Rooms where records are stored are locked when not in use. During regular business hours, rooms are unlocked but are controlled by on-site personnel. Individually identifiable records are kept in locked file cabinets or rooms under the direct control of the Project Director.

3. Procedural Safeguards: Names and other identifying particulars are deleted when data from original records are encoded for analysis. Data stored in computers is accessed through the use of keywords known only to authorized users. The computer terminals are in secured areas and keywords needed to access data files will be changed frequently.

4. Technical Safeguards: Computerized records are accessible only through a series of code or keyword commands available from and under direct control of the Project Director or his/her delegated representatives. The computer records are secured by a multiple level security system which is capable of controlling access to the individual data field level. Persons having access to the computer database can be restricted to a confined application which only permits a narrow "view" of the data. Data on computer files is accessed by keyword known only to authorized users who are NIH or contractor employees involved in work for the program.

These practices are in compliance with the standards of Chapter 45–13 of the HHS General Administration Manual, supplementary Chapter PHS hf: 45–13, the Department's Automated Information Systems Security Program Handbook, and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361): item 1300–B–9 for exposure incident files, which allows records to be destroyed after 10 years; and item 1300–B–10 for radiation exposure records, which does not allow disposal at this time. Refer to the NIH Manual Chapter for specific retention and disposition instructions.

SYSTEM MANAGER(S) AND ADDRESS:

Chief, Support Services Unit, Radiation Safety Services Section, Radiation Safety Branch, DS, ORS, Building 21, Room 104, 9000 Rockville Pike, Bethesda, Maryland 20892.

NOTIFICATION PROCEDURE:

To determine if a record exists, write to the system manager as listed above.

The requestor must also verify his or her identity by providing either a notarization of the request or a written certification that the requestor is whom he or she claims to be. The request should include: (a) Full name, and (b) appropriate dates of participation.

RECORD ACCESS PROCEDURE:

Same as notification procedures. Requestors should also reasonably specify the record contents being sought. Individuals may also request an accounting of disclosure of their records, if any.

CONTESTING RECORD PROCEDURE:

Contact the official under notification procedures above, reasonably identify the record, specify the information to be contested, and state the corrective action sought with supporting information. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Subject individual, previous employers and educational institutions, contractors.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 91–30194 Filed 12–23–91; 8:45 am]
BILLING CODE 4101–01–M

Centers for Disease Control

Privacy Act of 1974: Annual Publication of Systems of Records

AGENCY: Centers for Disease Control, HHS.

ACTION: Publication of minor changes to notices of systems of records.

SUMMARY: In accordance with the Office of Management and Budget Circular No. A–130, Appendix I, "Federal Agency Responsibilities for Maintaining Records About Individuals," the Centers for Disease Control (CDC) is publishing the table of contents and minor changes to its notices of systems of records.

SUPPLEMENTARY INFORMATION: CDC has completed the annual review of its systems of records and is publishing below the table of contents and those minor changes which affect the public's right or need to know, such as clarifications of categories of individuals covered by systems, changes in the system location of records, or the designation and address of system managers.

Centers for Disease Control

1. Table of Contents

A. The following CDC active systems of records were last published in the **Federal Register**, 51 FR 42449, November 24, 1986:

09–20–0000 Cooperative Mycoses Study, HHS/CDC/NCID.
09–20–0001 Certified Interpreting Physician File, HHS/CDC/NIOSH.
09–20–0055 Administrative Files for Research/Demonstration and Training Grants, and Cooperative Agreements Applications, HHS/CDC/NIOSH.
09–20–0059 Division of Training Mailing List, HHS/CDC/NIOSH.
09–20–0089 Studies of Treatment of Tuberculosis and Other Mycobacterioses, HHS/CDC/NCPS.
09–20–0090 Studies of Testing for Tuberculosis and Other Mycobacterioses, HHS/CDC/NCPS.
09–20–0096 Records of Tuskegee Study Health Benefit Recipients, HHS/CDC/NCPS.
09–20–0102 Alien Mental Waiver Program, HHS/CDC/NCPS.
09–20–0103 Alien Tuberculosis Follow-up Program, HHS/CDC/NCPS.
09–20–0106 Specimen Handling for Testing and Related Data, HHS/CDC/NCID.
09–20–0112 CDC Exchange Visitor and Guest Researcher Records, HHS/CDC/PMO.
09–20–0113 Epidemic Investigation Case Records, HHS/CDC/NCID.
09–20–0117 Medical and Test Record Results of Individuals Involved in NIOSH Laboratory Studies, HHS/CDC/NIOSH.
09–20–0118 Study at Work Sites Where Agents Suspected of Being Occupational Hazards Exist, HHS/CDC/NIOSH.
09–20–0136 Epidemiologic Studies and Surveillance of Disease Problems, HHS/CDC/NCID.
09–20–0137 Passport File, HHS/CDC/IHPO.
09–20–0138 Epidemic Intelligence Service Officers Files, HHS/CDC/EPO.
09–20–0147 Occupational Health Epidemiological Studies, HHS/CDC/NIOSH.
09–20–0149 Morbidity Studies in Coal Mining, Metal and Non-metal Mining and General Industry, HHS/CDC/NIOSH.
09–20–0153 Mortality Studies in Coal Mining, Metal and Non-metal Mining and General Industry, HHS/CDC/NOISH.
09–20–0154 Medical and Laboratory Studies, HHS/CDC/NIOSH.
09–20–0157 Clinical Laboratory Personnel Proficiency Test Results (Medicare), HHS/CDC/PHPPO.
09–20–0159 Records of Subjects in Certification, Testing, Studies of Personal Protective Devices, and Accident Investigations, HHS/CDC/NIOSH.
09–20–0160 Records of Subjects in Health Promotion and Education Studies, HHS/CDC/NCCDPHP.
09–20–0161 Records of Health Professionals in Disease Prevention and Control Training Programs, HHS/CDC/NCPS.
09–20–0162 Records of Subjects in Agent Orange, Vietnam Experience, and Selected Cancers Studies, HHS/CDC/NCEHIC.

B. The following active CDC systems were last published in the **Federal Register**, 51 FR 42368, November 24, 1986:

09–20–0163 Applicants for National Center for Health Statistics Technical Assistance, HHS/CDC/NCHS. (Formerly numbered 09–37–0009.)
09–20–0168 Curricular Vitae of Consultants to the National Center for Health Statistics, HHS/CDC/NCHS. (Formerly numbered 09–37–0014.)
09–20–0169 Users of Health Statistics, HHS/CDC/NCHS. (Formerly numbered 09–37–0014.)

C. The following CDC active systems were last published in the **Federal Register**, 49 FR 37692, September 25, 1984:

09–20–0164 Health and Demographic Surveys Conducted in Probability Samples of the United States Population, HHS/CDC/NCHS. (Formerly numbered 09–37–0010.)
09–20–0165 Health Manpower Inventories and Surveys, HHS/CDC/NCHS. (Formerly numbered 09–37–0011.)
09–20–0166 Vital Statistics for Births, Deaths, Fetal Deaths, Marriages, and Divorces Occurring in the United States During Each Year, HHS/CDC/NCHS. (Formerly numbered 09–37–0012.)
09–20–0167 Health Resources Utilization Statistics, HHS/CDC/NCHS. (Formerly numbered 09–37–0013.)

2. Four of CDC's centers have been retitled during 1991 to include "National" in their organizational names. The newly titled centers are:

National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP)
National Center for Environmental Health and Injury Control (NCEHIC)
National Center for Infectious Diseases (NCID)
National Center for Prevention Services (NCPS).

Additionally, the formerly titled Division of Tuberculosis Control, NCPS, has been renamed the Division of Tuberculosis Elimination.

These new organizational titles represent minor changes in the system name, system location, and system manager and address categories of the following systems: 09–20–0000, 0920–0089, 09–20–0090, 09–20–0096, 09–20–0102, 09–20–0103, 09–20–0106, 09–02–0113, 09–20–0136, 09–20–0160, 03–20–0161, and 09–20–0162. CDC will utilize the next comprehensive republication of notices to describe the systems in their entirety.

To provide an example of these changes, the revised categories of system 09–20–0136 are published below:

09–20–0136

SYSTEM NAME:

Epidemiologic Studies and Surveillance of Disease Problems, HHS/CDC/NCID. Minor alterations have been made to this system notice. The following categories are revised in their entirety:

* * * * *

SYSTEM LOCATION:

National Center for Infectious Diseases, Bldg. 1, Rm. 6013, Centers for Disease Control, 1600 Clifton Road, Atlanta, GA 30333.

San Juan Laboratories, National Center for Infectious Diseases, Centers for Disease Control, San Juan, Puerto Rico 00936.

National Center for Prevention Services, 1600 Freeway Park, Rm. 313, Centers for Disease Control, 1600 Clifton Road, Atlanta, GA 30333.

National Center for Environmental Health and Injury Control, Chamblee Bldg. 27, Centers for Disease Control, 1600 Clifton Road, Atlanta, GA 30333.

Epidemiology Program Office, Bldg. 1, Rm. 5009, Centers for Disease Control, 1600 Clifton Road, Atlanta, GA 30333.

Public Health Practice Program Office, Executive Park, Bldg. 24, Centers for Disease Control, 1600 Clifton Road, Atlanta, GA 30333.

National Center for Chronic Disease Prevention and Health Promotion, Koger/Rhodes Bldg., Room 4004, Centers for Disease Control, 1600 Clifton Road, Atlanta, GA 30333.

Federal Records Center, 1557 St. Joseph Avenue, East Point, GA 30344.

A list of contractor sites where individually identifiable data are currently located is available upon

request to the appropriate system manager.

* * * * *

SYSTEM MANAGER(S) AND ADDRESS:

Director, National Center for Infectious Diseases, Bldg. 1, Rm. 6013, Centers for Disease Control, 1600 Clifton Road, Atlanta, GA 30333.

Director, National Center for Prevention Services, 1600 Freeway Park, Rm. 310, Centers for Disease Control, 1600 Clifton Road, Atlanta, GA 30333.

Director, National Center for Environmental Health and Injury Control, Chamblee Bldg. 27, Centers for Disease Control, 1600 Clifton Road, Atlanta, GA 30333.

Director, Epidemiology Program Office, Bldg. 1, Rm. 5009, Centers for Disease Control, 1600 Clifton Road, Atlanta, GA 30333.

Director, Public Health Practice Program Office, Executive Park, Bldg. 24, Centers for Disease Control, 1600 Clifton Road, Atlanta, GA 30333.

Director, National Center for Chronic Disease Prevention and Health Promotion, Koger/Rhodes Bldg., Room 4004, Centers for Disease Control, 1600 Clifton Road, Atlanta, GA 30333.

Policy coordination is provided by: Director, Office of Program Support, Bldg. 1, Rm. 2011, Centers for Disease Control, 1600 Clifton Road, Atlanta, GA 30333.

* * * * *

3. The following systems are amended to reflect changes in the system location of records or the system manager and address category:

09–20–0102

SYSTEM NAME:

Alien Mental Waiver Program, HHS/CDC/NCPS.

Minor alterations have been made to this system notice. The following category is revised in its entirety:

* * * * *

SYSTEM LOCATION:

Medical Screening Section, Division of Quarantine, National Center for Prevention Services, 1644 Freeway Office Park, Rm. 1330, Centers for Disease Control, 1600 Clifton Road, Atlanta, GA 30333.

Federal Records Center, 1557 St. Joseph Avenue, East Point, GA 30344.

* * * * *

09–20–0112

SYSTEM NAME:

CDC Exchange Visitor and Guest Researcher Records, HHS/CDC/PMO.

Minor alterations have been made to this system notice. The following categories are revised in their entirety:

* * * * *

SYSTEM LOCATIONS:

Personnel Management Office, Bldg. 1, Rm. 1035, Centers for Disease Control, 1600 Clifton Road, Atlanta, GA 30333.

National Personnel Records Center (Civilian Personnel Records), 111 Winnebago Street, St. Louis, MO 63118.

* * * * *

SYSTEM MANAGER AND ADDRESS:

Director, Personnel Management Office, Bldg. 1, Rm. 1035, Centers for Disease Control, 1600 Clifton Road, Atlanta, GA 30333.

* * * * *

09–20–0160

SYSTEM NAME:

Records of Subjects in Health Promotion and Education Studies, HHS/CDC/NCCDPHP.

Minor Alterations have been made to this system notice. The following categories are revised in their entirety:

* * * * *

SYSTEM LOCATION:

National Center for Chronic Disease Prevention and Health Promotion, Koger/Rhodes Bldg., Rm. 4004, Centers for Disease Control, 1600 Clifton Road, Atlanta, GA 30333.

A list of contractor sites where individually identifiable data are currently located is available upon request to the system manager.

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SYSTEM MANAGER AND ADDRESS:

Director, National Center for Chronic Disease Prevention and Health Promotion, Koger/Rhodes Bldg., Rm. 4004, Centers for Disease Control, 1600 Clifton Road, Atlanta, GA 30333.

* * * * *

4. The following system notice has been updated to clarify and more accurately describe the categories of individuals and the purpose sections within the system:

09–20–0102

SYSTEM NAME:

Alien Mental Waiver Program, HHS/CDC/NCPS.

Minor alterations have been made to this system notice. The following categories are revised in their entirety:

* * * * *

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Immigrant aliens with waivers of excludability who have or have had a physical or mental disorder with associated behavior that may pose, or has posed, a threat to the property, safety, or welfare of the alien or others.

* * * * *

PURPOSE(S):

To comply with the requirements of section 212(g) of the Immigration and Nationality Act, the Centers for Disease Control (CDC) must receive and maintain medical records on aliens who apply for waivers of excludability due to a physical or mental disorder with associated harmful behavior. CDC is furnished with a copy of the alien's medical examination report and psychiatric/psychological evaluation and uses the information to process the initial applications for such waivers and for periodic medical surveillance and evaluation of individual cases.

* * * * *

Dated: October 24, 1991.

Robert L. Foster,

Acting Director, Office of Program Support, Centers for Disease Control.

[FR Doc. 91–26231 Filed 12–23–91; 8:45 am]

BILLING CODE 4160–18–M

Agency for Toxic Substances and Disease Registry

Privacy Act of 1974; Annual Publication of Systems of Records

AGENCY: Agency for Toxic Substances and Disease Registry, HHS.

ACTION: Publication of minor changes to notice of system of records.

SUMMARY: In accordance with the Office of Management and Budget Circular No. A–130, Appendix I, "Federal Agency Responsibilities for Maintaining Records About Individuals," the Agency for Toxic Substances and Disease Registry (ATSDR) is publishing the table of contents and minor changes to its notice of system of records.

SUPPLEMENTARY INFORMATION: ATSDR has completed the annual review of its system of records and is publishing below the table of contents and those minor changes which affect the public's right or need to know, such as changes in the system location of records, or the designation and address of system managers.

Agency for Toxic Substances and Disease Registry

1. Table of contents

The following system notice currently maintained by ATSDR was published in the **Federal Register**, 53 FR 30720, August 15, 1988:

09-19-0001 Records of Persons Exposed or Potentially Exposed to Toxic or Hazardous Substances, HHS/ATSDR/DHS.

2. System 09-19-0001 is amended to reflect changes in the system location of records and the designation and address of the system managers:

09-19-0001

SYSTEM NAME:

Records of Persons Exposed or Potentially Exposed to Toxic or Hazardous Substances, HHS/ATSDR/DHS.

Minor alterations have been made to this system notice. The following categories are revised in their entirety:

* * * * *

SYSTEM LOCATION:

Division of Health Studies, Agency for Toxic Substances and Disease Registry, Executive Park, Bldg. 35, 1600 Clifton Road, Atlanta, GA 30333.

Division of Health Assessment and Consultation, Agency for Toxic Substances and Disease Registry, Executive Park, Bldg. 31, 1600 Clifton Road, Atlanta, GA 30333.

Federal Records Center, 1557 St. Joseph Avenue, East Point, GA 30344.

Data are also located at contractor sites. A list of contractor sites where individually identified data are currently located is available upon request to the system manager.

* * * * *

SYSTEM MANAGER(S) AND ADDRESS:

Director, Division of Health Studies, Agency for Toxic Substances and Disease Registry, Executive Park, Bldg. 35, 1600 Clifton Road, Atlanta, GA 30333.

Director, Division of Health Assessment and Consultation, Agency for Toxic Substances and Disease Registry, Executive Park, Bldg. 31, 1600 Clifton Road, Atlanta, GA 30333.

Policy coordination is provided by: Deputy Assistant Administrator, Agency for Toxic Substances and Disease Registry, Chamblee Bldg. 5, 1600 Clifton Road, Atlanta, GA 30333.

* * * * *

Dated: October 24, 1991.

William L. Roper,

Administrator, Agency for Toxic Substances and Disease Registry.

[FR Doc. 91-26230 Filed 12-23-91; 8:45 am]

BILLING CODE 4160-70-M

Indian Health Service

Privacy Act of 1974; Annual Publication of Systems of Records

AGENCY: Indian Health Service, PHS, HHS.

ACTION: Publication of minor changes to system of records notices.

SUMMARY: In accordance with Office of Management and Budget Circular No. A-130, Appendix I, "Federal Agency Responsibilities for Maintaining Records About Individuals," the Indian Health Service (IHS), an agency of the Public Health Service (PHS), is publishing minor changes to the existing list of addresses of system of records 09-17-0001, "Health and Medical Records System, HHS/IHS/OHP."

SUPPLEMENTARY INFORMATION: IHS has completed the annual review of its systems of records. Since the publication of January 11, 1991, the only changes IHS has made that affect the Public's right or need to know are the address changes to Systems of Records 09-17-0001, "Health and Medical Records System, HHS/IHS/OHP."

Listed below are:

1. The Table of Contents of active IHS Systems of Records. The complete text of the Systems Notice was last published in the Office of the Federal Register's 1989 Biennial Compilation of Privacy Act Issuances:

Table of Contents:

09-17-0001 Health and Medical Records Systems, HHS/IHS/OHP.
09-17-0002 Indian Health Service Scholarship Programs, HHS/IHS/OHP.
09-17-0003 Indian Health Service Staff Credentials and Privileges Records, HHS/IHS/OHP.

2. The minor changes that have been made to the following IHS System of Records: 09-17-0001 Health and Medical Records Systems, HHS/IHS/OHP. Substitute Appendix 1 in its entirety as listed below:

* * * * *

Appendix 1—System Managers and IHS Locations Under Their Jurisdiction Where Records are Maintained:

Director, Aberdeen Area Indian Health Service, Federal Building, 115 Fourth Avenue, SE, Aberdeen, South Dakota 57401.
Director, Rapid City Service Unit, Rapid City Indian Hospital, Rapid City, South Dakota 57702.
Director, Cheyenne River Service Unit, Eagle Butte Indian Hospital, Eagle Butte, South Dakota 57625.
Director, Fort Berthold Service Unit, Minni-Tohe Indian Health Center, New Town, North Dakota 58763.
Director, Fort Totten Service Unit, Fort Totten Indian Health Center, Fort Totten, North Dakota 58335.
Director, Pine Ridge Service Unit, Pine Ridge Indian Hospital, Pine Ridge, South Dakota 57770.
Director, Kyle Indian Health Center, P.O. Box 540, Kyle, South Dakota 57752.
Director, Wanblee Indian Health Center, Wanblee, South Dakota 57577.
Director, Rosebud Service Unit, Rosebud Indian Hospital, Rosebud, South Dakota 57570.
Director, Sisseton-Wahpeton Service Unit, Sisseton Indian Hospital, Sisseton, South Dakota 57262.
Director, Wahpeton Indian School Health Center, Wahpeton, North Dakota 58075.
Director, Standing Rock Service Unit, Fort Yates Indian Hospital, Fort Yates, North Dakota 58538.
Director, McLaughlin Indian Health Center, McLaughlin, South Dakota 57642.
Director, Turtle Mountain Service Unit, Belcourt Indian Hospital, Belcourt, North Dakota 58316.
Director, Omaha-Winnebago Service Unit, Winnebago Indian Hospital, Winnebago, Nebraska 68071.
Director, Yankton-Wagner Service Unit, Wagner Indian Hospital, Wagner, South Dakota 57380.
Director, Crow Creek Service Unit, Ft. Thompson Indian Health Center, Ft. Thompson, South Dakota 57339.
Director, Pierre Indian School Health Center, c/o Ft. Thompson Indian Health Station, Ft. Thompson, South Dakota 57339.
Director, Lower Brule Indian Health Center, Lower Brule, South Dakota 57548.
Director, Bemidji Area Office, Indian Health Service, 203 Federal Building, Bemidji, Minnesota 56601.
Director, Eastern Michigan Service Unit, Kincheloe Indian Health Center, Kincheloe, Minnesota 49788.
Director, Leach Lake Service Unit, Cass Lake Indian Hospital, Cass Lake, Minnesota 56633.
Director, Inger Indian Health Station, Inger Route, Deer River, Minnesota 56636.
Director, Squaw Lake Indian Health Station, Squaw Lake, Minnesota 56681.
Director, Ball Club Indian Health Station, Ball Club, Minnesota 56622.
Director, Onigum Indian Health Station, Star Route, Walker, Minnesota 56484.
Director, Red Lake Service Unit, Red Lake Indian Hospital, Red Lake, Minnesota 56671.
Director, Ponemah Indian Health Station, Ponemah, Minnesota 56666.
Director, White Earth Service Unit, White Earth Indian Health Center, White Earth, Minnesota 56591.

Director, Naytahwaush Indian Health Station, Naytahwaush, Minnesota 56566.
Director, Pine Point Indian Health Station, White Earth, Minnesota 56591.
Director, Alaska Native Health Service, 250 Gambell Street, Anchorage, Alaska 99501.
Director, Anchorage Service Unit, PHS, Alaska Native Medical Center, 255 Gambell St., Anchorage, Alaska 99501.
Director, Alaska Native Health Center, St. George Island, Alaska 99660.
Director, Alaska Native Health Center, St. Paul Island, Alaska 99660.
Director, Barrow Service Unit, Barrow Alaska Native Hospital, Barrow, Alaska 99723.
Director, Southeast Area Regional Health Center, 3272 Hospital Drive, Juneau, Alaska 99801.
Director, Kotzebue Service Unit, Kotzebue Alaska Native Hospital, Kotzebue, Alaska 99752.
Director, Ketchikan Alaska Native Health Center, 3289 Tongass Avenue, Ketchikan, Alaska 99901.
Director, Annette Islands Service Unit, Metlakatla Alaska Native Health Center, Box 428, Metlakatla, Alaska 99926.
Director, Yukon-Kuskokwim-Delta Service Unit, Yukon-Kuskokwim-Delta Regional Hospital, Indian Health Service, Bethel, Alaska 99559.
Director, Albuquerque Area Indian Health Service, 505 Marquette, NW., Suite 1502, Albuquerque, New Mexico 87102–2163.
Director, Albuquerque Service Unit, Albuquerque Indian Hospital, 801 Vassar Drive, NE., Albuquerque, New Mexico 87106.
Director, Isleta Indian Health Center, PO. Box 429, Isleta, New Mexico 87022.
Director, Jemez Indian Health Center, PO Box 256, Jemez Pueblo, New Mexico 87024.
Chief Dental Program, IHS Dental Training Center, Southwestern Indian Polytechnical Inst., 9168 Coors Road, NW, PO Box 25927, Albuquerque, New Mexico 87125.
Director, Indian School Health Center, Southwestern Indian Polytechnical Inst., 9168 Coors Road, NW, PO Box 25927, Albuquerque, New Mexico 87125.
Director, Sandia Indian Health Station, Sandia, New Mexico 87047.
Director, Santa Ana Indian Health Station, P.O. Box 580, Bernalillo, New Mexico 87004.
Director, Zia Indian Health Station, General Delivery, San Ysidro, New Mexico 87053.
Director, Mescalero Service Unit, Mescalero Indian Hospital, PO Box 210, Mescalero, New Mexico 88340.
Director, Santa Fe Service Unit, Santa Fe Indian Hospital, 1700 Cerrillos Road, Santa Fe, New Mexico 87501.
Director, Dulce Indian Health Center, Dulce, New Mexico 87528.
Director, Taos Indian Health Center, Taos, New Mexico 87571.
Director, Santa Clara Indian Health Center, P.O. Box 1322, Espanola, New Mexico 87532.
Director, Santo Domingo Indian Health Station, Santo Domingo, New Mexico 87052.
Director, San Juan Indian Health Station, San Juan, New Mexico 87566.
Director, Cochiti Indian Health Station, Cochiti, New Mexico 87041.
Director, San Felipe Indian Health Station, General Delivery, San Felipe Pueblo, New Mexico 87001.
Director, Southern Colorado-Ute Service Unit, PO Box 778, Ignacio, Colorado 81137.
Director, Southern Ute Health Center, Ignacio, Colorado 81137.
Director, Ute Mountain Ute Health Center, Towaoc, Colorado 81334.
Director, White Mesa Indian Health Station, General Delivery, Towaoc, Colorado 81334.
Director, Zuni-Ramah Service Unit, Zuni Indian Hospital, Zuni, New Mexico 87327.
Director, Acoma-Canoncito-Laguna Service Unit, Acoma-Canoncito-Laguna Indian Hospital, PO Box 130, San Fidel, New Mexico 87049.
Director, Laguna Indian Health Center, PO Box 199, New Laguna, New Mexico 87038.
Director, Canoncito Indian Health Station, c/o Acoma-Canoncito-Laguna Indian Hospital, PO Box 130, San Fidel, New Mexico 87049.
Director, Billings Area Indian Health Service, P.O. Box 2143, 711 Central Avenue, Billings, Montana 59103.
Director, Blackfeet Service Unit, Browning Indian Hospital, Browning, Montana 59417.
Director, Heart Butte Indian Health Station, Heart Butte, Montana 59448.
Director, Crow Service Unit, Crow Indian Hospital, Crow Agency, Montana 59022.
Director, Lodge Grass Indian Health Center, Lodge Grass, Montana 59050.
Director, Pryor Indian Health Station, Pryor, Montana 59066.
Director, Flathead Service Unit, St. Ignatius Indian Health Center, St. Ignatius, Montana 59865.
Director, Polson Indian Health Center, 320–B 4th Avenue East, Polson, Montana 59860.
Director, Fort Belknap Service Unit, Harlem Indian Hospital, Harlem, Montana 59526.
Director, Hays Indian Health Station, Hays, Montana 59527.
Director, Fort Peck Service Unit, Poplar Indian Health Center, Poplar, Montana 59255.
Director, Wolf Point Indian Health Center, Wolf Point, Montana 59201.
Director, Wind River Service Unit, Fort Washakie Indian Health Center, Fort Washakie, Wyoming 82514.
Director, Arapahoe Indian Health Center, Arapahoe, Wyoming 82510.
Director, Northern Cheyenne Service Unit, Lame Deer Indian Health Center, Lame Deer, Montana 59043.
Director, Rocky Boy's Service Unit, Box Elder Indian Health Center, Box Elder, Montana 59521.
Director, Navajo Area Indian Health Service, P.O. Box G, Window Rock, Arizona 86515.
Director, Chinle Service Unit, P.O. Drawer P.H., Chinle, Arizona 86503.
Director, Tsailee Indian Health Center, P.O. Box 467, Tsailee, Arizona 86556.
Director, Pinon Indian Health Station, c/o Chinle Indian Hospital, P.O. Box P.H., Chinle, Arizona 86503.
Director, Rock Point Indian Health Station, c/o Chinle Indian Hospital, P.O. Box P.H., Chinle, Arizona 86503.
Director, Crownpoint Service Unit, Crownpoint Indian Hospital, P.O. Box 358, Crownpoint, New Mexico 87313.
Director, Pueblo Pintado Indian Health Station, c/o Crownpoint Indian Hospital, P.O. Box 358, Crownpoint, New Mexico 87313.
Director, Fort Defiance Service Unit, Fort Defiance Indian Hospital, P.O. Box 649, Fort Defiance, Arizona 86504.
Director, Gallup Service Unit, Gallup Indian Medical Center, P.O. Box 1337, Gallup, New Mexico 87301.
Director, Tohatchi Indian Health Center, P.O. Box 142, Tohatchi, New Mexico 87325.
Director, Fort Wingate Indian School Health Center, c/o Gallup Indian Medical Center, P.O. Box 1337, Gallup, New Mexico, 87301.
Director, Kayenta Service Unit, Kayenta Indian Health Center, P.O. Box 366, Kayenta, Arizona 86033.
Director, Inscription House Indian Health Center, P.O. Box 7397, Shonto, Arizona 86044.
Director, Dennehotso Indian Health Center, c/o Kayenta Indian Health Center, P.O. Box 368, Kayenta, Arizona 86033.
Director, Chilchinbeto Indian Health Station, c/o Kayenta Indian Health Center, P.O. Box 368, Kayenta, Arizona 86033.
Director, Shiprock Service Unit, Shiprock Indian Hospital, P.O. Box 160, Shiprock, New Mexico 87420.
Director, Teec Nos Pos Indian Health Center, P.O. Drawer D, Teec Nos Pos, Arizona 86514.
Director, Dzilth-Na-O-Dith-Le Indian Health Center, Star Route 4, Box 5400, Bloomfield, New Mexico 87413.
Director, Sanostee Indian Health Station, Shiprock Indian Hospital, P.O. Box 160, Shiprock, New Mexico 87420.
Director, Toadlena Indian Health Station, c/o Shiprock Indian Hospital, P.O. Box 160, Shiprock, New Mexico 87420.
Director, Tuba City Service Unit, Tuba City Indian Hospital, Tuba City, Arizona 86045.
Director, Dennebito Indian Health Station, c/o Tuba City Indian Hospital, Tuba City, Arizona 86045.
Director, Winslow Service Unit, Winslow Indian Health Center, P.O. Drawer 40, Winslow, Arizona 86047.
Director, Dilkon Indian Health Station, c/o Winslow Indian Health Center, P.O. Drawer 40, Winslow, Arizona 86047.
Director, Leupp Indian Health Station, c/o Winslow Indian Health Center, P.O. Drawer 40, Winslow, Arizona 86047.
Director, Oklahoma City Area Indian Health Service, 215 Dean A. McGee Street, NW., Oklahoma City, Oklahoma 73102–3477.
Director, Ada Service Unit, Carl Albert Indian Hospital, 1001 North Country Club Drive, Ada, Oklahoma 74820.
Director, Wewoka Indian Health Center, P.O. Box 1475, Wewoka, Oklahoma 74884.
Director, Claremore Service Unit, Claremore Comprehensive Indian Health Facility, West Will Rogers Boulevard & Moore, Claremore, Oklahoma 74017.
Director, Miami Indian Health Center, P.O. Box 1498, Miami, Oklahoma 74855.
Director, Clinton Service Unit, Clinton Indian Hospital, Route 4, Box 213, Clinton, Oklahoma 73601.
Director, Watonga Indian Health Center, P.O. Box 878, Watonga, Oklahoma 73772.

Director, Concho Indian Health Clinic, P.O. Box 150, Concho, Oklahoma 73022.
Director, Kansas Service Unit, Holton Indian Health Center, 100 West 16th Street, Holton, Kansas 66436.
Facility Director, Lawrence (Haskell) Indian Health Center, 2415 Massachusetts Avenue, Lawrence, Kansas 66044.
Director, Lawton Service Unit, Lawton Indian Hospital, Lawton, Oklahoma 73501.
Director, Anadarko Indian Health Center, P.O. Box 828, Anadarko, Oklahoma 73005.
Director, Carnegie Indian Health Center, P.O. Box 1120, Carnegie, Oklahoma 73105.
Director, Pawnee Service Unit, Pawnee Indian Health Center, Rural Route 2, Box 1, Pawnee, Oklahoma 74058.
Director, Pawhuska Indian Health Center, 715 Grandview, Pawhuska, Oklahoma 74056.
Director, White Eagle Indian Health Center, P.O. Box 2071, Ponca City, Oklahoma 74601.
Director, Shawnee Service Unit, Shawnee Indian Health Center, 2001 South Gordon Cooper Drive, Shawnee, Oklahoma 74801.
Director, Tahlequah Service Unit, W.W. Hastings Indian Hospital, 100 S. Bliss, Tahlequah, Oklahoma 74464.
Director, Phoenix Area Indian Health Service, 3738 N. 16th Street, Suite A, Phoenix, Arizona 85016–5981.
Director, Colorado River Service Unit, Parker Indian Hospital, Route 1, P.O. Box 12, Parker, Arizona 85344.
Director, Peach Springs Indian Health Center, Peach Springs, Arizona 86434.
Director, Chemehuevi Indian Health Clinic, Chemehuevi Valley, California 92363.
Director, Havasupai Indian Health Station, Supai, Arizona 86435.
Director, Fort Yuma Service Unit, Fort Yuma Indian Hospital, P.O. Box 1368, Fort Yuma, Arizona 85364.
Director, Sherman Indian School Health Center, 8934 Magnolia, Riverside, California 92503.
Director, Keams Canyon Service Unit, Keams Canyon Indian Hospital, P.O. Box 98, Keams Canyon, Arizona 86034.
Director, Second Mesa Indian Health Center, P.O. Box General Delivery, Second Mesa, Arizona 86043.
Director, Owyhee Service Unit, Owyhee Indian Hospital, P.O. Box 212, Owyhee, Nevada 89832.
Director, Southern Bank Indian Health Clinic, 1545 Silver Eagle Road, Elko, Nevada 89801.
Director, Phoenix Service Unit, Phoenix Indian Medical Center, 4212 North 16th St., Phoenix, Arizona 85016.
Director, Fort McDowell Indian Health Station, c/o Phoenix Indian Medical Center, 4212 North 16th Street, Phoenix, Arizona 86016.
Director, Salt River Indian Health Center, Route 1, Box 215, Scottsdale, Arizona 85256.
Director, Gila Crossing Indian Health Clinic, Route 1, Box 770, Laveen, Arizona 85339.
Director, San Lucy Indian Health Station, c/o Phoenix Indian Medical Center, 4212 North 16th Street, Phoenix, Arizona 85016.
Director, Phoenix Indian School Health Center, c/o Phoenix Indian Medical Center, 4212 North 16th St., Phoenix, Arizona 85016.
Director, Sacaton Service Unit, Sacaton Indian Hospital, Sacaton, Arizona 85247.
Director, San Carlos Service Unit, San Carlos Indian Hospital, San Carlos Arizona 85550.
Director, Bylass Indian Health Center, P.O. Box 208, San Carlos, Arizona 85550.
Director, Schurz Service Unit, Schurz Indian Hospital, Schurz, Nevada 89427.
Director, Stewart Indian Health Station, Stewart, Nevada 89437.
Director, Fort McDermitt Indian Health Station, P.O. Box 475, McDermitt, Nevada 89421.
Director, Pyramid Lake Indian Health Clinic, Nixon, Nevada 89424.
Director, Unitah and Ouray Service Unit, Fort Duchesne Indian Health Center, P.O. Box 160, Roosevelt, Utah 84066.
Director, Whiteriver Service Unit, Whiteriver Indian Hospital, Whiteriver, Arizona 85941.
Director, Cibicue Indian Health Center, Cibicue, Arizona 85941.
Director, Portland Area Indian Health Service, Room 476, Federal Building, 1220 Southwest Third Avenue, Portland, Oregon 97204–2892.
Director, Chimawa Indian Health Center, 3750 Hazelgreen Road, NE., Salem, Oregon 97303.
Director, Colville Service Unit, Colville Indian Health Center, Nespelem, Washington 99155.
Director, Inchelium Indian Health Center, Inchelium, Washington 99138.
Director, Fort Hall Service Unit, Fort Hall Indian Health Center, P.O. Box 317, Fort Hall, Idaho 83203.
Director, Northern Idaho Service Unit, Northern Idaho Indian Health Center, P.O. Drawer 367, Lapwai, Idaho 83540.
Director, Kamiah Indian Health Station, Kamiah, Idaho 83536.
Director, Coeur d'Alene Indian Health Station, Coeur d'Alene, Idaho 83814.
Director, Warm Springs Service Unit, Wellpinit Indian Health Center, P.O. Box 357, Wellpinit, Oregon 99040.
Director, Puget Sound Service Unit, Puget Sound Indian Health Station, 1212 South Indian Health Station, 1212 South Judkins, Seattle, Washington 98144.
Director, Yakima Service Unit, Yakima Indian Health Center, Route 1, Box 1104, Toppenish, Washington, 98948.
Director, Yellowhawk Service Unit, Yellowhawk Indian Health Center, P.O. Box 160, Pendleton, Oregon 97801.
Director, Taholah Service Unit, Taholah Indian Health Center, P.O. Box 219, Taholah, Washington 98587.
Director, Queets Indian Health Station, c/o Service Unit Director, Taholah Indian Health Center, P.O. Box 219, Taholah, Washington 98587.
Director, Neah Bay Service Unit, Neah Bay Indian Health Center, P.O. Box 418, Neah Bay, Washington 98357.
Director, Northwest Washington Service Unit, Lummi Indian Health Center, 2592 Kwina Road, Bellingham, Washington 98225.
Director, Office of Health Program Research & Development, Indian Health Service, 7900 S.J. Stock Road, Tucson, Arizona 85746–9352.
Director, Sells Service Unit, Sells Indian Hospital, P.O. Box 548, Sells, Arizona 85634.
Director, Santa Rosa Indian Health Center, HCR Box 700, Sells, Arizona 85634.
Director, San Xavier Indian Health Center, 7900 S. J. Stock Road, Tucson, Arizona 85746–9352.
Director, Nashville Area Office, Indian Health Service, Oak Towers Building, 1101 Kermit Drive, Suite 810, Nashville, Tennessee 37217–2191.
Director, Cherokee Service Unit, Cherokee Indian Hospital, Cherokee, North Carolina 28719.
Director, California Area Office, Indian Health Service, 2999 Fulton Avenue, Sacramento, California 95821.

Dated: December 5, 1991.

Everett R. Rhoades,

Assistant Surgeon General Director.

[FR Doc. 91 30045 Filed 12–23–91; 8:45 am]

BILLING CODE 4160–16–M

Health Resources and Services Administration

Privacy Act of 1974; Annual Publication of Systems of Records

AGENCY: Department of Health and Human Services; Public Health Service (PHS); Health Resources and Services Administration (HRSA).

ACTION: Publication of minor changes to systems of records notices.

SUMMARY: In accordance with the Office of Management and Budget Circular No. A–130, Appendix I, "Federal Agency Responsibilities for Maintaining Records About Individuals," HRSA is publishing minor changes to its notices of systems of records.

SUPPLEMENTARY INFORMATION: HRSA has completed the annual review of its systems of records and is publishing below those minor changes which affect the public's right or need to know, such as system deletions, title changes, and changes in the system location of records, or the address of systems managers.

Dated: October 22, 1991.

James A. Walsh,

Associate Administrator for Operations and Management.

Table of Contents

The following table of contents lists all currently active Privacy Act systems of records maintained by the Health Resources and Services Administration:

09–15–0001 Division of Federal Occupational and Beneficiary Health Services, Health and Counseling Records, HHS/HRSA/BHCDA.

09–15–0002 Record of Patients' Personal Valuables and Monies, HHS/HRSA/BHCDA.
09–15–0003 Contract Physicians and Consultants, HHS/HRSA/BHCDA.
09–15–0004 Federal Employee Occupational Health Data System, HHS/HRSA/BHCDA.
09–15–0007 Patients Medical Records System PHS Hospitals/Clinics, HHS/HRSA/BHCDA.
09–15–0008 Emergency Non-PHS Treatment Authorization File, HHS/HRSA/BHCDA.
09–15–0022 Accounts Receivable, HHS/HRSA/OA.
09–15–0026 Medical Fellowships and Educational Loans, HHS/HRSA/OA.
09–15–0028 PHS Clinical Affiliation Trainee Records, HHS/HRSA/BHCDA.
09–15–0029 PHS Beneficiary-Contract Medical/Health Care Records, HHS/HRSA/BHCDA.
09–15–0037 Public Health Service (PHS) and National Health Service Corps (NHSC) Health Care Provider Records System, HHS/HRSA/BHCDA.
09–15–0038 Disability Claims of the Nursing Student Loan Program, HHS/HRSA/BHPr.
09–15–0039 Disability Claims in the Health Professions Student Loan Program, HHS/HRSA/BHPr.
09–15–0040 Health Professions Student Loan Repayment Program, HHS/HRSA/BHPr.
09–15–0041 Health Professions Student Loan Cancellation, HHS/HRSA/BHPr.
09–15–0042 Physician Shortage Area Scholarship Program, HHS/HRSA/BHCDA.
09–15–0043 Cuban Loan Program, HHS/HRSA/OA.
09–15–0044 Health Educational Assistance Loan Program (HEAL) Loan Control Master File, HHS/HRSA/BHPr.
09–15–0045 Health Resources and Services Administration Loan Repayment/Debt Management Records Systems, HHS/HRSA/OA.
09–15–0046 Health Professions Planning and Evaluation, HHS/HRSA/OA.
09–15–0052 Nurse Practitioner and Midwifery Traineeship Program, HHS/HRSA/BHPr.
09–15–0054 National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners, HHS/HRSA/BHPr.
09–15–0055 Organ Procurement and Transplantation Network (OPTN) Data System, HHS/HRSA/BHRD.
09–15–0056 National Vaccine Injury Compensation Program, HHS/HRSA/BHPr.
09–15–0057 Scholarships for the Undergraduate Education of Professional Nurses Grant Programs, HHS/HRSA/BHPr.

Changes

09–15–0022

System name:

Accounts Receivable, HHS/HRSA/OA.

Minor changes have been made to this system notice. The following category should be revised:

* * * * *

System manager(s) and address:

Policy Coordination Official: Director, Division of Fiscal Services, Office of the Administrator (OA), Health Resources and Services Administration (HRSA), Room 16–05, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

Chief, Debt Management Branch, Division of Fiscal Services, HRSA/OA, Room 16A–09, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

Director, Gillis W. Long Hansen's Disease Center, Carville, LA 70721.

* * * * *

09–15–0026

System name:

Medical Fellowships and Educational Loans, HHS/HRSA/OA.

Minor changes have been made to this system notice. The following category should be revised:

* * * * *

System manager(s) and addresses:

Chief, General Accounting Branch, Division of Fiscal Services, Office of the Administrator, Health Resources and Services Administration, Room 16–16, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

09–15–0043

System name:

Cuban Loan Program, HHS/HRSA/OA. Minor changes have been made to this system notice. The following category should be revised:

* * * * *

System location:

Debt Management Branch, Division of Fiscal Services, Office of the Administrator, Health Resources and Services Administration, Room 16A–09, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

System manager(s) and address:

Chief, Debt Management Branch, Division of Fiscal Services, Office of the Administrator, Health Resources and Services Administration, Room 16A–09, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

* * * * *

09–15–0045

System name:

Health Resources and Services Administration Loan Repayment/Debt Management Records Systems, HHS/HRSA/OA.

Minor changes have been made to this system notice. The following categories should be revised:

* * * * *

System location:

Division of Fiscal Services, Office of the Administrator, Health Resources and Services Administration (HRSA), Room 16–05, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

Bureau of Health Professions, HRSA, Room 8–05, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

Bureau of Health Care Delivery and Assistance, HRSA, Room 7–05, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

Indian Health Service, Room 6–05, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

Grants Management Branch, National Institute on Drug Abuse, Room 10–25, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

Grants Management Branch, National Institute on Alcohol Abuse and Alcoholism, Room 16–86, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

Grants Management Branch, OPS, National Institute of Mental Health, Room 7C–23, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

Federal Assistance Accounting Branch, Division of Financial Management, National Institutes of Health, Room B1B04, Building 31, 9000 Rockville Pike, Bethesda, MD 20892.

Washington National Records Center, 4205 Suitland Road, Washington, DC 20409.

* * * * *

System manager(s) and address:

Policy Coordination Official: Associate Administrator for Operations and Management, Health Resources and Services Administration (HRSA) Room 14A–03, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

Chief, Debt Management Branch, Division of Fiscal Services, Office of the Administrator, HRSA, Room 16–09, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

Director, Office of Debt Management, Bureau of Health Professions, (HRSA), Room 8–05, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

Director, Division of Resource Management, Indian Health Service, Room 5A–38, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

* * * * *

09-15-0046

System name:

Health Professions Planning and Evaluation, HHS/HRSA/OA. Minor changes have been made to this system. The following categories should be revised:

* * * * *

System location:

This system of records is an umbrella system comprising separate sets of records located either in the organizations responsible for conducting evaluations or at the sites of programs or activities under evaluation. Locations include the Health Resources and Services Administration (HRSA) facilities in Rockville, Maryland, or facilities of contractors of HRSA. Write to the System Manager for a list of current locations.

Authority for maintenance of the system:

Authority is found in the following sections of the Public Health Service Act: Title III, Part D, "Primary Health Care" (42 U.S.C. 254b); Title VII, "Health Research and Training Facilities and Training of Professional Health Personnel" (42 U.S.C. 292a); Title VIII, "Nurse Education" (42 U.S.C. 296K); and Title XXVI, Section 2611, "Evaluation of Programs" (42 U.S.C. 300aaa-10). Authority is also found in Section 401 of the Health Care Quality Improvement Act of 1986 (42 U.S.C. 11101 note).

* * * * *

System manager(s) and address:

Deputy Director, Division of Information and Analysis, Office of Planning, Evaluation and Legislation, Health Resources and Services Administration, Room 14-33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

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Record access procedures:

To obtain access to your record, contact the System Manager and provide suitable identification, a reasonable description of the record and, if possible, information about the specific project. You may also request a list of accountable disclosures that have been made of your record.

Contesting record procedures:

To correct your record, contact the System Manager and provide (a) suitable identification, (b) reasonable description of the record, (c) the specific information you want corrected, and (d) a precise description of the correction with supporting justification. The right to contest records is limited to information which is incomplete, irrelevant, or untimely (obsolete).

[FR Doc. 91-25842 Filed 12-23-91; 8:45 am]

BILLING CODE 4160-15-M

Public Health Service

Food and Drug Administration

Privacy Act of 1974; Annual Publication of Systems of Records

AGENCY: Public Health Service (PHS), Department of Health and Human Services (HHS).

ACTION: Publication of minor changes to systems of records notices.

SUMMARY: FDA is publishing this document in accordance with Office of Management and Budget Circular No. A-130, Appendix I, "Federal Agency Responsibilities for Maintaining Records About Individuals."

SUPPLEMENTARY INFORMATION: FDA has completed the annual review of its systems of records and has made no changes which affect the public's right or need to know. Therefore, FDA is publishing below a table of contents only of all active systems of records in FDA. The last complete text of FDA's System Notices was published in the Office of the Federal Register's 1989 Annual Compilation of Privacy Act Issuances.

Dated: October 28, 1991.

Donald C. McLearn,

Acting Associate Commissioner for Public Affairs.

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[FR Doc. 91-26269 Filed 12-23-91; 8:45 am]

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federal register

Tuesday
December 24, 1991

Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 357

Orally Administered Drug Products for Relief of Symptoms Associated With Overindulgence in Food and Drink for Over-The-Counter Human Use; Tentative Final Monograph; Notice of Proposed Rulemaking

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 357

[Docket No. 82N-0166]

RIN 0905-AA06

Orally Administered Drug Products for Relief of Symptoms Associated With Overindulgence in Food and Drink for Over-the-Counter Human Use; Tentative Final Monograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking in the form of a tentative final monograph that would establish conditions under which over-the-counter (OTC) orally administered drug products for relief of symptoms associated with overindulgence in food and drink (drug products for the relief of symptoms of upset stomach due to overindulgence resulting from food and drink, and drug products to minimize or relieve hangover symptoms) are generally recognized as safe and effective and not misbranded. FDA is issuing this notice of proposed rulemaking after considering the report and recommendations of the Advisory Review Panel on OTC Miscellaneous Internal Drug Products and public comments on an advance notice of proposed rulemaking that was based on those recommendations. This proposal is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments, objections, or requests for oral hearing on the proposed regulation before the Commissioner of Food and Drugs by April 22, 1992. New data by December 24, 1992. Comments on the new data by February 24, 1993. Written comments on the agency's economic impact determination by April 22, 1992.

ADDRESSES: Written comments, objections, new data, or requests for oral hearing to the Dockets Management Branch (HFA-305), Food and Drug Administration, room 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 1, 1982 (47 FR 43540), FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), an advance notice of proposed rulemaking to establish a monograph for OTC orally administered drug products for relief of symptoms associated with overindulgence in alcohol and food, together with the recommendations of the Advisory Review Panel on OTC Miscellaneous Internal Drug Products (the Panel), which was the advisory review panel responsible for evaluating data on the active ingredients in these drug products. Interested persons were invited to submit comments by December 30, 1982. Reply comments in response to comments filed in the initial comment period could be submitted by January 31, 1983.

In accordance with § 330.10(a)(10), the data and information considered by the Panel were placed on public display in the Dockets Management Branch (address above), after deletion of a small amount of trade secret information.

In response to the advance notice of proposed rulemaking, two manufacturers, one consumer group, and one individual submitted comments. Copies of the comments received are on public display in the Dockets Management Branch.

In this tentative final monograph (proposed rule) to establish subpart J of part 357 (21 CFR part 357—subpart J), FDA states for the first time its position on the establishment of a monograph for OTC orally administered drug products for relief of symptoms associated with overindulgence in food and drink. The agency has changed the title of this monograph from drug products for * * * overindulgence in "alcohol and food" to * * * "food and drink." The agency considers the terms "food and drink" to be more inclusive of the use of these drug products. Final agency action on this matter will occur with the publication at a future date if a final monography, which will be a final rule establishing a monograph for these drug products.

This proposal constitutes FDA's tentative conclusions on OTC orally administered drug products for relief of symptoms associated with overindulgence in food and drink based on the agency's independent evaluation of the Panel's report and the comments received. Modifications have been made for clarity and regulatory accuracy and to reflect new information. Such new information has been placed on file in the Dockets Management Branch (address above). These modifications are reflected in the following summary of the comments and FDA's responses to them.

In the advance notice of proposed rulemaking for these products (47 FR 43540), the Panel's discussion and the recommended monograph were organized into four categories of active ingredients: (1) To minimize inebriation, (2) to minimize hangover symptoms, (3) for relief of hangover symptoms, and (4) for relief of symptoms of upset stomach due to overindulgence in the combination of alcohol and food. In the **Federal Register** of July 19, 1983 (48 FR 32872), the agency published a notice announcing that fructose or any other ingredient intended to minimize or prevent inebriation is a new drug and is required to be the subject of an approved new drug application (NDA) before marketing.

Activated charcoal, the only ingredient reviewed to reduce or minimize hangover, was placed in Category III in the advance notice of proposed rulemaking (47 FR 43540 at 43555). No additional data have been submitted to the agency to prove the effectiveness of activated charcoal in reducing or minimizing hangover. Therefore, activated charcoal remains in Category III for this use and is not further discussed in this document. However, the agency is proposing Category I labeling in this document in the event that data are submitted which result in the upgrading of activated charcoal to monograph status in the final rule.

In reviewing the Panel's recommendations on OTC drug products for relief of hangover symptoms and OTC drug products for relief of symptoms of upset stomach due to overindulgence in the combination of alcohol and food, the agency recognizes that this rulemaking significantly overlaps other rulemakings in the OTC drug review. For example, the Panel's recommendation on OTC drug products for relief of hangover symptoms consists of a combination of ingredients involving ingredients already classified as Category I in other OTC drug monographs: Antacid (21 CFR part 331), stimulant (21 CFR part 340), and internal analgesic (proposed 21 CFR part 343) (see the **Federal Register** of November 16, 1988, 53 FR 46204). To avoid unnecessary monograph duplication, the agency will not propose to establish a separate monograph for products for relief of hangover symptoms that contain these classes of ingredients. Instead, the agency is proposing to amend the final monographs for OTC antacid (21 CFR part 331) and stimulant (21 CFR part 340) drug products, and is amending the tentative final monograph for OTC internal analgesic drug

products to include appropriate conditions for relief of hangover symptoms. These proposals are published elsewhere in this issue of the Federal Register.

Similarily, the claim for relief of symptoms of upset stomach due to overindulgence in the combination of food and drink overlaps claims contained in the antacid rulemaking. Therefore, the agency is proposing to amend the final monograph for OTC antacid drug products to include appropriate conditions for relief of the symptoms of upset stomach due to overindulgence in food and drink.

Therefore, this tentative final monograph will include only ingredients, such as bismuth subsalicylate, that are not included in other OTC drug final monographs or ongoing rulemakings and only for claims related to relief of upset stomach associated with overindulgence in food and drink. For further discussion, see comment 1 below.

For the sake of clarity and comprehensiveness, all issues raised in comments to the advance notice of proposed rulemaking for OTC orally administered drug products for relief of symptoms associated with overindulgence in alcohol and food (47 FR 43540) are being addressed in this tentative final monograph. However, any comments received in response to the proposed amendments to the monographs for OTC antacid, internal analgesic, or stimulant drug products, published elsewhere in this issue of the Federal Register, will be addressed in the respective rulemaking, as appropriate.

The OTC drug procedural regulations (21 CFR 330.10) now provide that any testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process before the establishment of a final monograph. Accordingly, FDA will no longer use the terms "Category I" (generally recognized as safe and effective and not misbranded), "Category II" (not generally recognized as safe and effective or misbranded), and "Category III" (available data are insufficient to classify as safe and effective, and further testing is required) at the final monograph stage, but will use instead the terms "monograph conditions" (old Category I) and "nonmonograph conditions" (old Categories II and III). This document retains the concepts of Categories I, II, and III at the tentative final monograph stage.

The agency advises that the conditions under which the drug products that are subject to this monograph would be generally recognized as safe and effective and not misbranded (monograph conditions) will be effective 12 months after the date of publication of the final monograph in the Federal Register. On or after that date, no OTC drug product that is subject to the monograph and that contains a nonmonograph condition, i.e., a condition that would cause the drug to be not generally recognized as safe and effective or to be misbranded, may be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved application. Further, any OTC drug product subject to this monograph that is repackaged or relabeled after the effective date of the monograph must be in compliance with the monograph regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with the monograph at the earliest possible date.

If the agency determines that any labeling for a condition included in the final monograph should be implemented sooner than the 12-month effective date, a shorter deadline may be established. Similarly, if a safety problem is identified for a particular nonmonograph condition, a shorter deadline may be set for removal of that condition from OTC drug products.

All "OTC Volumes" cited throughout this document refer to the submissions made by interested persons pursuant to the call-for-data notices published in the Federal Register of November 16, 1973 (38 FR 31697) and August 27, 1975 (40 FR 38179) or to additional information that has come to the agency's attention since publication of the advance notice of proposed rulemaking. The volumes are on public display in the Dockets Management Branch (address above).

I. The Agency's Tentative Conclusions on the Comments

1. Two comments questioned the appropriateness of the term "food and drink overindulgence reliever" as a statement of identity. The comments noted that OTC drug monographs normally use a term such as "antacid" or "analgesic" that describes the pharmacological category or principal intended action of the active ingredient(s) as a statement of identity. One comment requested that terms such as "antacid" or "analgesic" be permitted as alternatives to the Panel's recommended statement of identity. The comment added that consumers are familiar with current statements of identity and proposing new ones may confuse consumers or mislead them into thinking that a product has been changed. The other comment requested that the statement of identity be changed from "food and drink overindulgence reliever" to "upset stomach remedy," stating that this phrase is concise, accurate, and provides the consumer with a better understanding of the product's intended use. The comment added that the Panel's proposed statement of identity is very lengthy and could create labeling space problems, particularly for a product with multiple indications.

The agency acknowledges that statements of identity are normally expressed in terms of the general pharmacological category(ies) or principal intended action(s) of the active ingredients in the products, in accord with 21 CFR 201.61. As pointed out by the comments, the statement of identity "food and drink overindulgence reliever," which was recommended by the Panel, does not conform to the usual practice set forth in § 201.61 and is potentially confusing to consumers. The agency believes that a shorter, more concise statement of identity can be used, and the agency is proposing to revise the statement of identity. The agency believes that the statement of identity "upset stomach remedy" suggested by one of the comments is preferable. However, the agency believes this phrase would be more appropriate if the term "remedy" was replaced with the term "reliever" because the term "reliever" more accurately describes the intended effect of such products than the term "remedy." Therefore, the agency is proposing the term "upset stomach reliever" as the statement of identity for the products covered by this tentative final monograph.

The suggestion by one comment that widely recognized statements of identity such as "antacid" or "analgesic" be allowed as alternatives to the proposed statement of identity is not being included in this document. As discussed in the preamble to this document, if the action of an ingredient or combination of ingredients in relieving "upset stomach" or "overindulgence in food and drink" is that of an antacid, then those ingredients are more appropriately covered under the monograph for OTC antacid drug products and would bear the statement of identity appropriate to that monograph, i.e., "antacid", as the comment requested. (See notice of proposed rulemaking for Antacid Drug

Products for Over-the-Counter Human Use published elsewhere in this issue of the **Federal Register**.)

As discussed above, the agency is limiting this rulemaking to those ingredients, such as bismuth subsalicylate, that are not covered by the rulemaking for OTC antacid drug products. (See section II. paragraph A. 1.)

2. One comment urged that combination drug products containing sodium citrate and sodium acetylsalicylate in solution be exempted from the Panel's recommended analgesic overdose warning regarding ringing in the ears in § 357.952(c)(4)(ii) (47 FR 43540 at 43559). The comment argued that this combination is incapable of producing potentially toxic blood levels of salicylate. The comment stated that, in comparison with aspirin administered in other dosage forms, this combination product produces more rapid, high salicylate blood levels, an increased salicylate excretion rate with increasing dosages due to alkalinization of the urine by the sodium citrate, and a leveling off of plasma salicylate concentration. In support of this argument, the comment referred to a study of Leonards (Ref. 1) in which large repeated doses of the combination drug product or aspirin were administered to human subjects and plasma salicylate levels were determined. Four 325-milligram (mg) tablets of aspirin were given every 2 hours up to a maximum of 20 tablets in 8 hours. Four tablets of the combination drug product, containing an amount of salicylate equivalent to the aspirin, were also given every 2 hours, up to a maximum of 28 tablets in 12 hours. The plasma salicylate levels reached 2 hours after the last dose were 188 milligrams per liter (mg/L) for the combination product and 300 mg/L for aspirin. Plasma salicylate reached approximately 200 mg/L for the combination product at 10 hours, but had dropped to 180 mg/L at 14 hours. Therefore, the comment contended that this combination drug product will not reach toxic plasma salicylate levels, regardless of the dose taken, and the proposed warning should not be applicable to this particular combination drug product.

The agency has reviewed the cited study (Ref. 1) and concludes that the data are inadequate to establish that toxic blood levels of salicylate cannot be achieved by a combination product containing sodium citrate and sodium acetylsalicylate. The study includes two separate dosage tests conducted on two groups of subjects. In the first test, 12 normal adult subjects were given 1,300 mg (4 tablets of 325 mg each) of aspirin followed by 6 ounces (oz) of water every 2 hours until 6.5 grams (g) (20 tablets) were taken. One week later, an equivalent dose of the combination product dissolved in 6 oz of water was administered to the same 12 subjects. Blood samples were taken at 0, 2, 4, 6, 8, and 10 hours after the first dose and total salicylate in plasma was determined. Plasma salicylate levels of approximately 300 mg/L for the aspirin and 188 mg/L for the combination product were reported 2 hours after the last dose. The test indicated that plasma salicylate levels after repeated administration of large amounts of aspirin continued to rise to approach toxic levels, while the plasma salicylate levels after repeated administration of large amounts of the combination drug product appeared to level off at the still safe concentration of 188 mg/L. The second dose test assessed the peak plasma salicylate levels of six subjects given the same amount of combination drug product as used in the first test; the subjects were given the drug every 2 hours until seven doses had been taken. Peak plasma salicylate levels of approximately 200 mg/L were reached 10 hours after the first dose, with the level dropping to approximately 180 mg/L at 14 hours.

The agency acknowledges that the Leonards study shows that subjects who received the combination drug product had lower plasma salicylate levels after 10 hours than those who received aspirin. However, as the Advisory Review Panel on OTC Internal Analgesic and Antirheumatic Drug Products (Internal Analgesic Panel) discussed in its report (42 FR 35346 at 35379), there is great variability of salicylate metabolism and elimination in normal individuals. Thus, the plasma salicylate levels observed in the small sample of subjects used in the Leonards study (Ref. 1) could not be considered to be representative of the population on a whole. Further, the Internal Analgesic Panel pointed out that no correlation between response and plasma levels has been established (42 FR 35346 at 35373). The Internal Analgesic Panel further noted that correlation between product formulation, drug blood levels achieved, and the onset of pharmacological effect is not understood (42 FR 35346 at 35374). Thus, even if a correlation between dose and plasma salicylate levels can be established, a correlation between plasma salicylate levels and salicylate effect (i.e., ringing in the ears) must still be established. The agency concurs with the Panel's findings. (See also comment 39 of the tentative final monograph for OTC internal analgesic, antipyretic, and antirheumatic drug products published in the **Federal Register** of November 16, 1988, 53 FR 46204 at 46222.)

Therefore, based on the above discussion, the agency is not exempting combination drug products containing sodium citrate and sodium acetylsalicylate from the warning regarding ringing in the ears. Combinations of antacids and internal analgesics, including combinations of sodium citrate and sodium acetylsalicylate in solution, are primarily being handled in the rulemaking for OTC internal analgesic drug products and not in this rulemaking. (See also comment 1.) Such a combination drug product would, therefore, be required to bear the warning proposed in the tentative final monograph for OTC internal analgesic, antipyretic, and antirheumatic drug products in § 343.50(c)(1)(v)(A), published in the **Federal Register** of November 16, 1988 (53 FR 46204 at 46256), which states "If ringing in the ears or a loss of hearing occurs, consult a doctor before taking any more of this product." Such products would not be permitted to bear the warning recommended by the Miscellaneous Internal Panel in § 357.952(c)(4)(ii) of the advance notice of proposed rulemaking for OTC orally administered drug products for the relief of symptoms associated with overindulgence in alcohol and food.

Reference

(1) Leonards, J. R., "Safety of Alka-Seltzer in Very Large Doses as Evidenced by Plasma Salicylate Levels," draft of unpublished study, OTC Volume 170198, Docket No. 82N-0166, Dockets Management Branch.

3. One comment urged that the claims "fast relief" and "speedy relief" be permitted in the labeling of a drug product containing a combination of sodium citrate and sodium acetylsalicylate in solution. The comment claimed that substantial scientific data submitted to the Panel on this product clearly demonstrate that the product provides faster symptomatic relief than other dosage forms. The comment pointed out that, because this product is already in solution when ingested, the dissolution step that is necessary for other dosage forms before absorption occurs is eliminated. Thus, the acetylsalicylate and total salicylate quickly become available. The comment added that the rapid gastric emptying (to the duodenum) that occurs produces both early and high peak plasma levels of acetylsalicylate (Ref. 1). The comment also contended that the drug product

provides instant acid neutralization, thereby instantly relieving the symptoms that are acid related or mediated (Ref. 2). The comment argued that the statements "speedy relief" and "fast relief" simply convey, in layman's language, truthful and informative information that the product acts relatively promptly. The comment concluded that there is no basis for prohibiting use of these claims.

In comment 42 of the tentative final monograph for OTC internal analgesic, antipyretic, and antirheumatic drug products (53 FR 46204 at 46223), the agency addressed the claim of quicker analgesic benefits for antacid and analgesic combination drug products in a solution dosage form. In that document, the agency concurred with the Internal Analgesic Panel that no well-controlled studies exist to prove that absorption rates will produce therapeutically different results with regard to onset, intensity, or incidence of relief of symptoms. Thus, in the absence of supporting data, such claims were placed in Category III. Further, while the data submitted by the comment (Ref. 1) do indicate that the product provides rapid neutralization of stomach acid, the data do not prove or disprove that rapid acid neutralization will result in clinically significant differences in the onset, intensity, or incidence of relief of symptoms associated with overindulgence of food and/or drink. Therefore, the agency is placing the label claims "fast relief" and "speedy relief" in Category III until further data supporting such claims are provided.

References

(1) OTC Volume 170189, pp. 18–21.
(2) OTC Volume 170189, pp. 17–18.

4. One comment agreed with the Panel's recommendation at 47 FR 43547 that combination products containing antacids and aspirin labeled "for the relief of upset stomach due to overindulgence in the combination of food and drink, when accompanied by a headache or other minor aches and pains" be appropriately buffered so that the final dosage form at least meets the buffering capacity of an antacid final dosage form. The comment also supported the Panel's recommended deletion of the proposed caution against the use of aspirin-containing products in the presence of "gastric distress" for products containing an adequate amount of antacids, and urged the agency to adopt the Panel's recommendation. The comment summarized the Panel's discussion and other data on this subject in support of its contention that highly buffered analgesic-antacid combinations, such as sodium acetylsalicylate and sodium citrate in solution, do not damage the stomach or gastric mucosa, or cause gastrointestinal bleeding (Ref. 1).

In comment 47 of the tentative final monograph for OTC internal analgesic, antipyretic, and antirheumatic drug products (53 FR 46204 at 46226), the agency discussed analgesic-antacid labeling claims for aspirin-antacid drug products and stated that such combination drug products for ingestion as a solution should provide at least 5 milliequivalents (mEq) of acid neutralizing capacity as specified in § 331.10(a) of the OTC antacid final monograph (21 CFR part 331). In this document, the agency continues to support that position.

The safety of highly buffered aspirin solutions and aspirin-antacid combinations and the effects of such products on the gastrointestinal tract was also discussed in comment 47 of the tentative final monograph for OTC internal analgesic, antipyretic, and antirheumatic drug products (53 FR 46226). The agency concluded in that document that such combination products should bear warnings against their use by persons who have persistent or recurring stomach problems, such as acid indigestion, or who have ulcers or bleeding problems as stated in the following proposed warning in the tentative final monograph for OTC internal analgesic, antipyretic, and antirheumatic drug products (§ 343.50(c)(1)(v)(B)): "Do not take this product if you have stomach problems (such as heartburn, upset stomach, or stomach pain) that persist or recur, or if you have ulcers or bleeding problems, unless directed by a doctor." Because the combination products mentioned by the comment are primarily being handled in the rulemaking for OTC internal analgesic drug products, they would be required to bear this proposed warning.

Reference

(1) Comment No. C0005, Appendix A, Docket No. 82N–0166, Dockets Management Branch.

5. One comment criticized the Panel's reasoning for allowing use for relief of alcoholic hangover symptoms of a combination product that contains active ingredients from at least two of the following three drug categories: Analgesic, antacid, and stimulant. The comment disagreed with the Panel's conclusion that because these ingredients have been reviewed extensively by other Panels and found effective for treating the various symptoms that comprise a hangover, it is unnecessary to require clinical studies to prove the effectiveness of the combination products used to treat hangover (47 FR 43540 at 43551). The comment expressed the belief that, in lieu of clinical studies, and Panel based its recommendation on the fact that over the years people have found it convenient to treat hangover with these combination products.

The comment questioned whether it is correct to classify a product as generally recognized as safe and effective based primarily on the fact that similar products have been used for this purpose for many years. The comment argued that unsafe products such as analgesics containing phenacetin and ineffective products such as hair growing agents were marketed for years and later found to be either unsafe or ineffective. The comment expressed the opinion that the Panel's action with respect to hangover remedies provides evidence that the agency is willing to abandon its legal responsibilities under the OTC drug review because these recommendations are irrational, lack proof of sound scientific evidence, set a precedent for the issuance of further unsound monographs, and allow the marketing of unnecessary and irrational products. The comment concluded that until substantial evidence exists for a given product or ingredient, the agency should not add new products to the OTC market or add new indications on old products.

A second comment recommended that the agency adopt the Panel's determination that the combination of the internal analgesic sodium acetylsalicylate and the antacid sodium citrate in solution is safe and effective in relieving the symptoms of a hangover. The comment expressed the opinion that this determination is fully supported by the scientific literature and years of experience with the product.

The agency believes that the first comment overlooks a number of important considerations in the Panel's evaluation of combination products containing antacids, analgesics, and stimulants to treat hangover symptoms. It was not the Panel's intention to permit random combinations of ingredients in a simple product for a simple indication, but rather to recognize that the term "hangover" referred to a commonly recognized symptom complex that is composed of symptoms for which Category I ingredients that exist in the antacid, internal analgesic, and stimulant monographs can be used. Although acknowledging that no study had been done to determine the relative frequency of hangover symptoms in a

large population, the Panel compiled a list of symptoms that included nausea, heartburn, thirst, tremor, disturbance of equilibrium, fatigue, general aches and pain, headache, dullness and/or depression, and irritability (47 FR 43540 at 43551). The Panel then proposed to allow combination products containing an internal analgesic(s) to treat the headache and general aches, an antacid(s) to treat the gastric distress, and a stimulant (caffeine) to treat the dullness or fatigue. The Panel proposed that any combination of ingredients from two or more of these categories of drugs, was a Category I hangover reliever.

The Panel believed it would be justifiable to combine active ingredients to treat these separate symptoms if the combination met the agency's requirements (47 FR 43540 at 43551). In its "General Guidelines for OTC Drug Combination Products" (Ref. 1), the agency has provided that Category I active ingredients from different therapeutic categories may be combined to treat different symptoms concurrently only if each ingredient is present within its established safe and effective dosage range and the combination meets the OTC drug combination policy in all other respects. In this case, the different symptoms treated concurrently are part of the symptom complex. The OTC drug combination policy, as stated in 21 CFR 330.10(a)(4)(iv) of the OTC drug regulations, includes the provisions that combining of the active ingredients does not decrease the safety or effectiveness of any of the individual active ingredients, and the combination provides rational concurrent therapy for a significant proportion of the target population.

The agency agrees that a symptom complex known as "hangover" does exist and that its symptoms vary widely from individual to individual. In reviewing the data on hangover symptoms cited by the Panel (Refs. 2 through 6), the agency agrees that many of the symptoms that form the complex are treatable with combination products containing internal analgesic, antacid, or stimulant ingredients. The agency further agrees that certain symptoms of a hangover are relieved by the combination of the internal analgesic sodium acetylsalicylate and the antacid sodium citrate in solution.

The agency notes, however, that in recommending combination products to treat hangover symptoms, the Panel failed to adequately consider that caffeine stimulates gastric secretion of hydrochloric acid (Refs. 7 through 13). The ability of caffeine to significantly increase hydrochloric acid secretion is mentioned in standard medical reference textbooks (Refs. 7 and 8) and was reported by Roth and Ivy (Ref. 13) as early as 1944. McArthur, Hogan, and Isenberg (Ref. 9) undertook a study to determine the effect of nine commonly ingested beverages on gastric acid secretion in humans. Six healthy subjects were each studied on 11 separate days and in random order. Test substances were 3 types of soda water, 3 different brands of instant coffee, tea, milk, and beer. The control was water. The results were considered significantly different for each beverage versus the control ($p<0.05$). The authors stated that this study indicates that each of the beverages tested is a potent stimulus of gastric acid secretion regardless of its caffeine content. Studies by Cohen and Booth (Ref. 10) likewise demonstrated that caffeine stimulates gastric acid secretion and reduces the competence of the lower esophageal sphincter in healthy subjects. Noting that caffeine is a potent stimulant of gastric secretion in man, Roth and Ivy (Ref. 13) conducted experiments to determine the synergistic effect of caffeine upon alcohol. They observed that the gastric secretory response to the combined action of alcohol plus caffeine was an average of 65.9 percent greater than the response produced when alcohol and caffeine were given separately. Further, the response to the combination of alcohol and caffeine was prolonged, lasting approximately 70 minutes longer than that of the individual ingredients.

The Advisory Review Panel on OTC Sedative, Tranquilizer, and Sleep-aid Drug Products (Sleep-aid Panel) noted in its advance notice of proposed rulemaking for OTC nighttime sleep-aid, daytime sedative, and stimulant drug products (December 8, 1975, 40 FR 57292 at 57324 to 57325) that caffeine stimulates gastric secretion in man. While that Panel stated that normal doses of caffeine (i.e., 100 mg) did not seem to cause irritation of the gastrointestinal tract, the agency notes that the target population considered by that Panel in its assessment of the safety and effectiveness of caffeine as an OTC stimulant did not specifically include individuals that already had some degree of stomach or gastrointestinal irritation or upset due to overindulgence in alcohol and/or food. Further, the Sleep-aid Panel did not give any consideration to the safety of caffeine in patients with already high levels of stomach acid.

In view of caffeine's documented effect in stimulating gastric secretions, the agency does not believe that combination products containing both caffeine, which stimulates hydrochloric acid secretion, and an antacid, which reduces the concentration of hydrochloric acid and treats the symptoms associated with high levels of hydrochloric acid, are rational. Therefore, the agency is reversing the Panel's Category I recommendation and is placing in Category II all combination products for the treatment of hangover that contain both an antacid ingredient and caffeine, a stimulant ingredient. The agency is not aware of any marketed OTC drug combination products, other than hangover remedies, that contain both stimulant and antacid ingredients.

Analgesic-antacid combinations are currently included in the tentative final monograph for OTC internal analgesic, antipyretic, and antirheumatic drug products, published in the **Federal Register** of November 16, 1988 (53 FR 46204). The agency does not see a need to establish a separate monograph for drug products for the relief of hangover symptoms when this indication can readily be incorporated into the rulemaking for OTC internal analgesic, antipyretic, and antirheumatic drug products.

Accordingly, the agency is proposing to eliminate further consideration of drug products for the relief of hangover in this document and is instead proposing elsewhere in this issue of the **Federal Register** to amend the internal analgesic tentative final monograph in § 343.20 by adding new paragraph (b)(5), to read as follows:

(b) * * *

(5) *Internal analgesic and stimulant combinations.* Any internal analgesic ingredient identified in § 343.10(a) or (b)(1) of this chapter may be combined with any stimulant ingredient identified in § 340.10 of this chapter provided the product bears labeling indications in accordance with § 343.60(b)(6).

The agency is also proposing to amend the labeling for products containing a combination of an internal analgesic and an antacid to include claims for the relief of symptoms of hangover and/or overindulgence in food and drink and to include a warning for products for relief of hangover symptoms in § 343.60 by revising paragraphs (b)(2) and (b)(4) and (c) and by adding new paragraphs (b)(6) and (c)(1), to read as follows:

(b) * * *

(2) *For permitted combinations identified in § 343.20(b)(1).* The indications are the following: "For the temporary relief of minor aches and pains with" (select one or more of the following: "heartburn," "sour stomach,"

or "acid indigestion") (which may be followed by: "and upset stomach associated with" (select one or more of the following, as appropriate: "this symptom," "these symptoms," "hangover," or "overindulgence in food and drink."))

* * * * *

(4) *For permitted combinations identified in § 343.20(b)(3).* The indications are the following: "For the temporary relief of minor aches and pains with" (select one or more of the following: "heartburn," "sour stomach," or "acid indigestion") (which may be followed by: "and upset stomach associated with" (select one or more of the following, as appropriate: "this symptom," "these symptoms," "hangover," or "overindulgence in food and drink")) and "Also may be used for the temporary relief of minor aches and pains alone" (which may be followed by one or more of the following: ("such as associated with" (select one or more of the following: "a cold," "the common cold," "sore throat," "headache," "toothache," "muscular aches," "backache," "the premenstrual and menstrual periods" (which may be followed by "dysmenorrhea)"), or "premenstrual and menstrual cramps" (which may be followed by: "(dysmenorrhea)")), ("and for the minor pain from arthritis"), and ("and to reduce fever.")

* * * * *

(6) *For permitted combinations identified in § 343.20(b)(5).* The indications are the following: "For the temporary relief of minor aches and pain associated with a hangover. Helps restore mental alertness or wakefulness when experiencing fatigue or drowsiness associated with a hangover."

* * * * *

(c) *Warnings.* The labeling of the product states, under the heading "Warnings," the warnings(s) for each ingredient in the combination, as established in the warnings sections of the applicable OTC drug monographs, unless otherwise stated in this paragraph.

(1) *For permitted combinations identified in § 343.20(b)(1) and (b)(3) when labeled for the relief of the symptoms of hangover.* "Do not use for more than 2 days for a hangover unless directed by a doctor."

(2) [Reserved]

The agency is further proposing elsewhere in this issue of the **Federal Register** to amend the OTC stimulant final monograph by adding a new section § 340.20 to subpart B to include combinations of stimulant and nonstimulant active ingredients, to read as follows:

Section 340.20 *Permitted combinations of active ingredients.*

The following combinations are permitted provided each active ingredient is present within the established dosage limits and the product is labeled in accordance with § 340.60.

(a) *Combinations containing a stimulant active ingredient and an internal analgesic active ingredient(s).* (See § 343.20(b)(5) of this chapter.)

(b) [Reserved]

The agency is also proposing to add new § 340.60 to supart C, to read as follows:

Section 340.60 *Labeling of permitted combinations of active ingredients.*

Statements of identity, indications, warnings, and directions for use, respectively, applicable to each ingredient in the product may be combined to eliminate duplicative words or phrases so that the resulting information is clear and understandable.

(a) *Statement of identity.* For a combination drug product that has an established name, the labeling of the product states the established name of the combination drug product, followed by the statement of identity for each ingredient in the combination, as established in the statement of identity sections of the applicable OTC drug monographs. For a combination drug product that does not have an established name, the labeling of the product states the statement of identity for each ingredient in the combination, as established in the statement of identity sections of the applicable OTC drug monographs.

(b) *Indications.* The labeling of the product states, under the heading "Indications," the indication(s) for each ingredient in the combination, as established in the indications sections of the applicable OTC drug monographs, unless otherwise stated in this paragraph. Other truthful and nonmisleading statements describing only the indications for use that have been established and listed in this paragraph may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) *For permitted combinations containing a stimulant and an internal analgesic active ingredient identified in § 340.20(a).* The indications in § 343.60(b)(6) of this chapter should be used.

(2) [Reserved]

(c) *Warnings.* The labeling of the product states, under the heading "Warnings," the warning(s) for each ingredient in the combination, as established in the warnings sections of the applicable OTC drug monographs, unless otherwise stated in this paragraph.

For permitted combinations containing any stimulant ingredient identified in § 340.20. The following warning should be used instead of the warnings in §§ 340.50(c)(2) and 343.50(c)(1) of this chapter: "For occasional use only. Do not use for more than 2 days for a hangover unless directed by a doctor. Not intended for use as a substitute for sleep. If fatigue or drowsiness persists or continues to recur, consult a" (select one of the following: "physician" or "doctor").

(d) *Directions.* The labeling of the product states, under the heading "Directions," directions that conform to the directions established for each ingredient in the directions sections of the applicable OTC drug monographs, unless otherwise stated in this paragraph. When the time intervals or age limitations for administration of the individual ingredients differ, the directions for the combination product:

(1) May not contain any dosage that exceeds those established for any individual ingredient in the applicable OTC drug monograph(s), and

(2) May not provide for use by any age group lower than the highest minimum age limit established for any individual ingredient.

The agency is further proposing elsewhere in this issue of the **Federal Register** to amend § 331.30 of the OTC antacid monograph by revising paragraph (b), to read as follows:

(b) *Indications.* The labeling of the product states, under the heading "Indications," the following: "For the relief of" (select any or all of the following: "heartburn," "sour stomach," and/or "acid indigestion") (which may be followed by the statement: "and upset stomach associated with" (select one or more of the following, as appropriate "this symptom," "these symptoms," or "overindulgence in food and drink.") Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in this paragraph, may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

In proposing the above labeling the agency hopes to eliminate consideration of overlapping claims for the same ingredients subject to different OTC drug monographs and, at the same time, limit combinations to those which have been proven scientifically sound and justified.

References

(1) Food and Drug Administration "General Guidelines for OTC Drug Combination Products, September 1978, "Docket No. 78D–0322, Dockets Management Branch.

(2) Collins, W. E., "Performance Effects of Alcohol Intoxication and Hangover at Ground Level and at Simulated Altitude," Aviation Space and Environmental Medicine, 51:327–335, 1980.

(3) Anylian, G. H., J. Dorn, and J. Swerdlow, "The Manifestation, Aetiology and Assessment of Ethanol-Induced Hangover," South African Medical Journal, 54:193–198, 1978.

(4) Khan, M. A., K. Jensen, and H. J. Krough, "Alcohol-Induced Hangover: A Double-Blind Comparison of Pyritinol and Placebo in Preventing Hangover Symptoms," Quarterly Journal of Studies on Alcohol, 34:1195–1201, 1973.

(5) Chapman, L. F., "Experimental Induction of Hangover," Quarterly Journal of

Studies on Alcohol, Supplement No. 5:67–86, May 1970.

(6) Damrau, F., and E. Liddy, "Hangovers and Whiskey Congeners: Comparison of Whiskey and Vodka," Journal of the National Medical Association, 52:262–265, 1960.

(7) Rall, T. W., "Drugs Used in the Treatment of Asthma," in "The Pharmacological Basis of Therapeutics," 8th ed., edited by A. G. Gilman, et al., Pergamon Press, New York, p. 623, 1990.

(8) Ivey, K. J., and J. L. A. Roth, "Drug and Chemical-Induced Injuries of the Stomach," Chapter 64 in "Bockus Gastroenterology," 4th ed., Edited by J. E. Berk, W. B. Saunders Co., Philadelphia, pp. 975 and 995, 1985.

(9) McArthur, K., D. Hogan, and J. I. Isenberg, "Relative Stimulatory Effects of Commonly Ingested Beverages on Gastric Acid Secretion in Humans," Gastroenterology, 83:199–203, 1982.

(10) Cohen, S., and G. H. Booth, Jr., "Gastric Acid Secretion and Lower-Esophageal-Sphincter Pressure in Response to Coffee and Caffeine," The New England Journal of Medicine, 293:897–899, 1975.

(11) Friedman, G. D., A. B. Siegelaub, and C. C. Seltzer, "Cigarettes, Alcohol, Coffee and Peptic Ulcer," The New England Journal of Medicine, 290:469–473, 1974.

(12) Debas, H. T., et al., "Caffeine-Stimulated Acid and Pepsin Secretion: Dose-Response Studies," Scandinavian Journal of Gastroenterology, 6:453–457, 1971.

(13) Roth, J.A., and A.C. Ivy, "The Synergistic Effect of Caffeine Upon Histamine in Relation to Gastric Secretion," American Journal of Physiology, 142:107–113, 1944.

6. One comment supported the Panel's recommendation for modified warnings for hangover relief drug products containing internal analgesic ingredients. Specifically, the comment agreed with the Panel that the 10-day limitation on use of the drug (see recommended warning for OTC internal analgesic drug products in § 343.50(c)(1)(i) at 42 FR 35493) and that the caution regarding use of an internal analgesic with prescription drugs taken for diabetes, gout, and arthritis (see recommended warning for OTC internal analgesic drug products in § 343.50(c)(3)(v) at 42 FR 35493) should be deleted. The comment supported the Panel's reasoning that such modifications of the warnings recommended for OTC internal analgesic drug products were appropriate because hangover is considered an acute, self-limiting condition that does not require warnings applicable to products subject to more prolonged use. The comment also supported the Panel's recommendation to delete, as too vague, the words "or other symptoms" from the warning for OTC internal analgesic drug products (proposed in § 343.50(c)(3)(ii) at 42 FR 35493), that states "Stop taking this product if ringing in the ears or other symptoms occur."

The agency disagrees with the Panel's recommendations for deleting or modifying the warnings applicable to internal analgesic ingredients contained in products for the treatment of hangover. While hangover is generally an acute self-limiting condition, the symptom complex can be experienced for periods of several days, either as a result of excessive and physically harmful consumption of alcoholic beverages or as a result of the consumption of alcohol aggravating some other disease or condition. If the condition persists for more than 2 days, the individual should seek medical guidance and not continue to rely on a hangover remedy for symptomatic relief.

As discussed in comment 5, the agency is not including combinations of products for the relief of hangover in this rulemaking, but elsewhere in this issue of the **Federal Register** the agency is amending the tentative final monograph for OTC internal analgesic drug products to include internal analgesic/antacid and internal analgesic/stimulant combinations for the relief of hangover symptoms. Accordingly, the agency concludes that combination products for relief of hangover symptoms that contain an internal analgesic ingredient should bear the applicable warnings required under § 343.50 of the internal analgesic tentative final monograph, and the interaction warning concerning use with prescription drugs used to treat gout, diabetes, and arthritis.

With regard to the 10-day limitation on use of internal analgesics, the agency notes that when the limitation for the use of the individual ingredients in a combination drug product differ, the labeling for the combination product may not exceed any maximum limit established for the individual ingredients in the applicable OTC drug monographs. Antacids have a 2-week limitation of use (21 CFR 331.30(c)(1)), internal analgesics have a 10-day limitation of use (proposed 21 CFR 343.50(c)(1); 53 FR 46204 at 46256), and stimulants, although recommended only for occasional use, have no established limitation of use (21 CFR Part 340). Therefore, any combination product for relief of hangover symptoms containing an internal analgesic would be limited to use for no more than 10 days. However, as discussed above, the agency believes that individuals who require the use of a hangover relief product for more than 2 days should seek medical guidance. Therefore, the agency proposes to limit the use of any OTC hangover relief drug product to 2 days unless directed by a doctor. The agency is proposing to amend § 343.60 of the tentative final monograph for OTC internal analgesic, antipyretic, and antirheumatic drug products by adding new paragraph (c)(1), to read as follows:

(1) *For permitted combinations identified in § 343.20(b)(1) and (3) when labeled for the relief of the symptoms of hangover.* "Do not use for more than 2 days for a hangover unless directed by a doctor."

The agency is also proposing to amend § 340.60 of the final monograph for OTC stimulant drug products by adding new paragraph (c), to read as follows:

(c) *Warnings.* The labeling of the product states, under the heading "Warnings," the warning(s) for each ingredient in the combination, as established in the warnings sections of the applicable OTC drug monographs, unless otherwise stated in this paragraph. The following warning should be used for permitted combinations containing any stimulant ingredient identified in § 340 20 instead of the warnings in §§ 340.50(c)(2) and 343.50(c)(1) of this chapter: "For occasional use only. Do not use for more than 2 days for a hangover unless directed by a doctor. Not intended for use as a substitute for sleep. If fatigue or drowsiness persists or continues to recur, consult a" (select one of the following: "physician" or "doctor").

The agency points out that the term "other symptoms," was deleted, as requested by the comment, from the warning in § 343.50(c)(3)(ii) in the tentative final monograph for OTC internal analgesic, antipyretic, and antirheumatic drug products which was published in the **Federal Register** of November 16, 1988 (53 FR 46204 at 46257).

7. One comment concurred with the Panel that no ingredient has been demonstrated to be both safe and effective to prevent or reduce inebriation. However, the comment expressed concern that since the advance notice of proposed rulemaking was published, numerous sobering agents have been advertised and readied for marketing. According to the comment, many of these products have sought to avoid FDA's OTC drug approval procedures by claiming that they are food supplements. The comment was also greatly concerned that these products would be misused to "make drinking safer" or "to control drunken driving." The comment added that, before such products are allowed to be marketed, evidence must be presented that demonstrates benefits for all potential users of the product, e.g., men and women, all ages (over 16), light to heavy drinkers (including alcoholics), and that includes test-simulating real-

life activities such as driving. The comment stated that unless a product is shown to eliminate all sensory and cognitive impairment resulting from alcohol ingestion, FDA should reject any use of the term "sober" to describe or name such a product. The comment stated that, if such products were approved, their labeling should warn against reliance on the product (1) to improve driving capabilities after drinking or (2) to increase one's alcohol consumption. The comment concluded that any approved labeling should not mislead drinking consumers into believing that drinking and driving are somehow compatible or that sustained, excessive drinking does not pose substantial health, social, and safety risks.

The agency shares the comment's concerns. In the **Federal Register** of July 19, 1983 (48 FR 32872), FDA declared any such product to be a new drug and, as such, it must be the subject of an approved NDA before marketing occurs. This notice stated that products intended to minimize or prevent inebriation may present a health hazard, particularly when motorists rely on unsubstantiated claims that a product will prevent or minimize an inebriated state, and such products could give persons who consume alcoholic beverages and then drive a motor vehicle a false sense of security. Therefore, all testing and labeling for any such product will have to be approved by the agency before such a product may be legally marketed. No such drug products are currently marketed, and the agency is not aware of any product intended to prevent or reduce inebriation being marketed as a food supplement.

II. The Agency's Tentative Conclusions on the Panel's Report

A. Summary of Ingredient Categories and Testing of Category II and Category III Conditions

1. Summary of Ingredient Categories

The agency has reviewed all claimed active ingredients submitted to the Panel, as well as other data and information available at this time, and has made some changes in the categorization of active ingredients recommended by the Panel for drug products for relief of symptoms associated with overindulgence in food and drink. In addition, as discussed in the comments above, the agency is limiting the rulemaking for OTC overindulgence drug products to only those ingredients that have not been adequately covered by other OTC drug rulemakings for similar claims related to relief of symptoms of upset stomach associated with overindulgence in food and drink or hangover. As a convenience to the reader, the following list is included as a summary of the categorization of overindulgence active ingredients recommended by the Panel and the proposed categorization by the agency. Where the ingredient has been classified in another rulemaking, that rulemaking and the classification therein is stated.

CATEGORIZATION OF INGREDIENTS

Active ingredients	Panel				Agency
	Overindulgence	[1] Hangover reliever	Hangover minimizer	Inebriation minimizer	
Acetaminophen		I			Internal analgesic (I).
Aluminum hydroxide		I			Antacid (I).
Aluminum hydroxide gel		I			Antacid (I).
Aspirin		I			Internal analgesic (I).
Bismuth subsalicylate	I				I.
Caffeine		I			Stimulant (I).
Charcoal, activated			III		III.
Fructose				III	[2] II (New Drug).
Magnesium carbonate		I			Antacid (I).
Magnesium trisilicate		I			Antacid (I).
Sodium acetylsalicylate in solution		I			Internal analgesic (I).
Sodium citrate in solution	I	I			Antacid (I).

[1] The Panel classified these ingredients in Category I for hangover relief only when used in combination as provided in parts 331, 340, and 343.
[2] All products intended to prevent or minimize inebriation were classified as new drugs in the Federal Register of July 19, 1983 (48 FR 32872).

2. Testing of Category II and Category III Conditions

Interested persons may communicate with the agency about the submission of data and information to demonstrate the safety or effectiveness of any overindulgence ingredient or condition included in this review by following the procedures outlined in the agency's policy statement published in the **Federal Register** of September 29, 1981 (46 FR 47740) and clarified April 1, 1983 (48 FR 14050). That policy statement includes procedures for the submission and review of proposed protocols, agency meetings with industry or other interested persons, and agency communications on submitted test data and other information.

B. Summary of the Agency's Changes in the Panel's Recommendations

FDA has considered the comments and other relevant information and concludes that it will tentatively adopt the Panel's report and recommended monograph with the changes described in FDA's responses to the comments above and with other changes described in the summary below. A summary of the changes made by the agency follows:

(1) The agency is limiting the rulemaking for OTC overindulgence drug products to include only those ingredients that have not been adequately covered by other OTC drug rulemakings that address similar claims related to relief of symptoms of hangover or overindulgence in food and drink. (See comments 1 and 5, above, and section II. A. 1.)

(2) The agency has revised the phrase "due to overindulgence in the combination of alcohol and food" recommended by the Panel in the proposed headings for § 357.910 and § 357.950 to read "due to overindulgence in food and drink." The use of the word "combination" is redundant and unnecessary.

(3) The agency is proposing a new statement of identity "upset stomach reliever," for products labeled for the relief of overindulgence in food and drink, (See comment 1.)

(4) The agency is not including combinations containing bismuth subsalicylate and nonsalicylate analgesic active ingredients labeled for the relief of symptoms of upset stomach due to overindulgence in food and drink in this tentative final monograph. While such combinations were recommended as Category I in the advance notice of proposed rulemaking (47 FR 43540 at 43558), the agency is unaware of any data supporting the safety and effectiveness of such combinations. Further, the agency is unaware that such combinations have ever been marketed. Because no combinations of active ingredients for relief of symptoms of upset stomach due to overindulgence in food and drink are currently included in this rulemaking, the agency is not including the Panel's recommended § 357.920 *Permitted combinations of active ingredients* in the tentative final monograph.

(5) The agency is adding, as § 357.950(c)(2), the warning proposed in § 343.50(c)(1)(vi) of the tentative final monograph for OTC internal analgesic, antipyretic, and antirheumatic drug products (53 FR 46204 at 46256) "Do not take this product if you are allergic to salicylates (including aspirin) unless directed by a doctor."

(6) The agency is adding a warning appearing as § 357.950(c)(3) "Do not use for more than 2 days unless directed by a doctor" to reflect safety considerations and the dose limitation for bismuth subsalicylate-containing products addressed in the tentative final monograph for OTC antidiarrheal drug products (51 FR 16138 at 16143 and 16149).

The agency is also modifying the Panel's warning recommended in § 357.950(c)(1)(ii) for products containing bismuth subsalicylate labeled for the relief of symptoms of upset stomach due to overindulgence in food and drink to conform to a similar warning the agency proposed for other salicylates in the tentative final monograph for OTC internal analgesic, antipyretic, and antirheumatic drug products in § 343.50(c)(1)(v)(C) (53 FR 46204 at 46256). The warning, appearing as § 357.950(c)(4) in this tentative final monograph, reads as follows: "*Drug Interaction Precaution:* Do not take this product if you are taking a prescription drug for anti coagulation (thinning the blood), diabetes, gout, or arthritis unless directed by a doctor."

(7) The agency is combining several indications statements recommended by the Panel in § 357.956(b) for drug products to minimize hangover symptoms and is slightly revising the directions paragraph for bismuth subsalicylate labeled for relief of symptoms of upset stomach due to overindulgence in food and drink in § 357.950(d) to conform with the format of other recently published tentative final monographs.

(8) In an effort to simplify OTC drug labeling, the agency proposed in a number of tentative final monographs to substitute the word "doctor" for physician in OTC drug monographs on the basis that the word "doctor" is more commonly used and better understood by consumers. Based on comments received to these proposals, the agency has determined that final monographs and any applicable OTC drug regulation will give manufacturers the option of using either the word "physician" or the word "doctor." This tentative final monograph proposes that option.

The agency has examined the economic consequences of this proposed rulemaking in conjunction with other rules resulting from the OTC drug review. In a notice published in the **Federal Register** of February 8, 1983 (48 FR 5806), the agency announced the availability of an assessment of these economic impacts. The assessment determined that the combined impacts of all the rules resulting from the OTC drug review do not constitute a major rule according to the criteria established by Executive Order 12291. The agency therefore concludes that no one of these rules, including this proposed rule for OTC overindulgence drug products, is a major rule.

The economic assessment also concluded that the overall OTC drug review was not likely to have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act (Pub. L. 96–354). That assessment included a discretionary regulatory flexibility analysis in the event that an individual rule might impose an unusual or disproportionate impact on small entities. However, this particular rulemaking for OTC overindulgence drug products is not expected to pose such an impact on small businesses. Therefore, the agency certifies that this proposed rule, if implemented, will not have a significant economic impact on a substantial number of small entities.

The agency invited public comment in the advance notice of proposed rulemaking regarding any impact that this rulemaking would have on OTC overindulgence drug products. No comments on economic impacts were received. Any comments on the agency's initial determination of the economic consequences of this proposed rulemaking should be submitted by April 22, 1992. The agency will evaluate any comments and supporting data that are received and will reassess the economic impact of this rulemaking in the preamble to the final rule.

The agency has determined under 21 CFR 25.24(c)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Interested persons may, on or before April 22, 1992, submit to the Dockets Management Branch (address above) written comments, objections, or requests for oral hearing before the Commissioner on the proposed regulation. A request for an oral hearing must specify points to be covered and time requested. Written comments on the agency's economic impact determination may be submitted on or before April 22, 1992. Three copies of all comments, objections, and requests are to be submitted, except that individuals may submit one copy. Comments, objections, and requests are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Comments, objections, and requests may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. Any scheduled oral hearing will be announced in the **Federal Register**.

Interested persons, on or before December 24, 1992, may also submit in writing new data demonstrating the safety and effectiveness of those conditions not classified in Category I. Written comments on the new data may be submitted on or before February 24, 1993. These dates are consistent with the time periods specified in the agency's final rule revising the procedural regulations for reviewing and classifying OTC drugs, published in the **Federal Register** of September 29, 1981 (46 FR 47730). Three copies of all data and comments on the data are to be submitted, except that individuals may submit one copy, and all data and comments are to be identified with the docket number found in brackets in the heading of this document. Data and comments should be addressed to the Dockets Management Branch (address above). Received data and comments may also be seen in the office above

between 9 a.m. and 4 p.m., Monday through Friday.

In establishing a final monograph, the agency will ordinarily consider only data submitted prior to the closing of the administrative record on February 24, 1993. Data submitted after the closing of the administrative record will be reviewed by the agency only after a final monograph is published in the **Federal Register**, unless the Commissioner finds good cause has been shown that warrants earlier consideration.

List of Subjects in 21 CFR Part 357

Labeling, Over-the-counter drugs, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 357 be amended as follows:

PART 357—MISCELLANEOUS INTERNAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR part 357 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371).

2. A new Subpart J is added to Part 357 to read as follows:

Subpart J—Orally Administered Drug Products for Relief of Symptoms Associated with Overindulgence in Food and Drink

Sec.

Subpart J—Orally Administered Drug Products for Relief of Symptoms Associated with Overindulgence in Food and Drink

§ 357.901 Scope.

(a) An over-the-counter drug product for the relief of symptoms of upset stomach due to overindulgence in food and drink or to minimize hangover symptoms, in a form suitable for oral administration is generally recognized as safe and effective and is not misbranded if it meets each condition in this subpart and each general condition established in § 330.1 of this chapter.

(b) References in this subpart to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

§ 357.903 Definitions.

As used in this subpart:

(a) *Upset stomach due to overindulgence in food and drink.* A condition which occurs as a result of overindulgence in food and drink and consists of a group of symptoms which includes heartburn, fullness, and nausea.

(b) *Hangover.* A condition consisting of a complex of symptoms involving the gastrointestinal, neurologic, and metabolic system that follows recent acute excessive alcohol ingestion. The symptoms may include nausea, heartburn, thirst, tremor, disturbances of equilibrium, fatigue, generalized aches and pains, headache, dullness, and/or depression or irritability.

§ 357.910 Active ingredients for the relief of symptoms of upset stomach due to overindulgence in food and drink.

The active ingredient of the product is bismuth subsalicylate when used within the dosage limits established in § 357.950(d).

§ 357.916 Active ingredients to minimize hangover symptoms. [Reserved]

§ 357.950 Labeling of drug products for the relief of symptoms of upset stomach due to overindulgence in food and drink.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as an "upset stomach reliever."

(b) *Indications.* The labeling of the product states, under the heading "Indications," any of the phrases listed in paragraph (b) of this section, as appropriate. Other truthful and nonmisleading statements, describing only the indications for use that have been established in this paragraph, may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act:

(1) "For the relief of upset stomach due to overindulgence in food and drink."

(2) "For the relief of upset stomach associated with" (select one or more of the following: "nausea," "heartburn," and "fullness") "due to overindulgence in food and drink."

(c) *Warnings.* The labeling of the product contains the following warnings under the heading "Warnings":

(1) "This product contains salicylate. If taken with other salicylate-containing preparations (such as aspirin) and ringing in the ears occurs, discontinue use."

(2) "Do not take this product if you are allergic to salicylates (including aspirin) unless directed by a doctor."

(3) "Do not use for more than 2 days unless directed by a doctor."

(4) "*Drug Interaction Precaution.* Do not take this product if you are taking a prescription drug for anticoagulation (thinning the blood), diabetes, gout, or arthritis unless directed by a doctor."

(d) *Directions.* The labeling of the product contains the following information under the heading "Directions" for products containing bismuth subsalicylate identified in § 357.910. Adults and children 12 years of age and over: oral dosage is 0.525 gram every ½ to 1 hour, as required, not to exceed 4.2 grams or 8 doses in 24 hours. Children under 12: consult a doctor.

(e) The word "physician" may be substituted for the word "doctor" in any of the labeling statements in this section.

§ 357.956 Labeling of drug products to minimize hangover symptoms.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as a "hangover minimizer."

(b) *Indications.* The labeling of the product states, under the heading "Indications," the following: (Select one of the following: "To minimize," "For minimizing," or "Helps to minimize") "the symptoms of a hangover caused by alcoholic beverages." Other truthful and nonmisleading statements, describing only the indications for use that have been established in this paragraph, may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or deliver for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(c) *Warnings.* [Reserved]

(d) *Directions.* [Reserved]

Dated: November 1, 1991.

Michael R. Taylor,

Deputy Commissioner for Policy

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Tuesday
December 24, 1991

Part IV

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 331

Antacid Drug Products for Over-the-Counter Use; Proposed Amendment to the Monograph; Notice of Proposed Rulemaking

DEPARTMENT OF HEALTH AND HUMAN SERVICES

21 CFR Part 331

[Docket No. 88N-003U]

RIN 0905-AA06

Antacid Drug Products for Over-the-Counter Human Use; Proposed Amendment to the Monograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking that would amend the final monograph for over-the-counter (OTC) antacid drug products to include conditions for the relief of upset stomach associated with overindulgence in food and drink. FDA is issuing this notice of proposed rulemaking after considering the report and recommendations of the Advisory Review Panel on OTC Miscellaneous Internal Drug Products and public comments on the advance notice of proposed rulemaking for orally administered drug products for relief of symptoms associated with overindulgence in alcohol and food for OTC human use that was based on those recommendations. This proposal is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments, objections, or requests for oral hearing on the proposed regulation before the Commissioner of Food and Drugs by April 22, 1992. New data by December 24, 1992. Comments on the new data by February 24, 1993. Written comments on the agency's economic impact determination by April 22, 1992.

ADDRESSES: Written comments, objections, new data, or requests for oral hearing to the Dockets Management Branch (HFA-305), Food and Drug Administration, room 1-23, 12420 Parklawn Dr., Rockville, MD 30857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 4, 1974 (39 FR 19862), FDA issued a final monograph for OTC antacid drug products (21 CFR part 331). Section 331.15(b) (21 CFR 331.15(b)) of the monograph provides for the combination of antacid and analgesic ingredients. In the **Federal Register** of August 31, 1982 (47 FR 38481), the agency concluded that antacid drug products may be labeled for relief of upset stomach associated with heartburn, sour stomach, and acid indigestion, and amended the monograph to include this claim in § 331.30(b). The agency recognized that "upset stomach" is a general term used by consumers to describe clusters of symptoms (47 FR 38481 at 38482). The agency also noted that terms such as "heartburn" may be used by consumers to describe gastrointestinal distress resulting from other causes such as overindulgence in food and drink. However, the agency stated that as of August 31, 1982. antacids have not been shown to relieve components of the upset stomach syndrome other than those for which labeling has been specified in the antacid monograph (47 FR 38481 at 38483).

Subsequent to the publication of the final rule for OTC antacid drug products and the amendment of the antacid monograph described above, the agency published the advanced notice of proposed rulemaking for orally administered drug products for relief of symptoms associated with overindulgence in alcohol and food for OTC human use (October 1, 1982, 47 FR 43540). In that notice, the Advisory Review Panel on OTC Miscellaneous Internal Drug Products (the Panel) reviewed data on drug products containing antacid, analgesic, and stimulant ingredients in various combinations and recommended conditions for their safe and effective OTC use. The Panel concluded that the following combinations of Category I ingredients were safe and effective for use in relief of the symptoms of hangover: (1) Antacids and analgesics, (2) antacids and stimulants, (3) analgesics and stimulants and (4) antacids, analgesics, and stimulants. The Panel also recommended that the antacid ingredient sodium citrate in solution was safe and effective for use in the relief of upset stomach associated with overindulgence in the combination of alcohol and food. In addition, the Panel recommended that sodium citrate in solution for this use could be combined with any Category I internal analgesic ingredient in 21 CFR Part 343 (proposed in the **Federal Register** of November 16, 1988 53 FR 46204). The Panel added that if the product contains aspirin (as identified in Part 343), the finished product must meet the acid neutralizing requirements of § 331.10 of the antacid monograph (21 CFR 331.10).

The agency notes, however, that in recommending combination products to treat hangover symptoms, the Panel failed to adequately consider that caffeine stimulates gastric secretion of hydrochloric acid (Refs. 1 through 7). The ability of caffeine to significantly increase hydrochloric acid secretion is mentioned in standard medical reference textbooks (Refs. 1 and 2) and was reported by Roth and Ivy (Ref. 7) as early as 1944. McArthur, Hogan, and Isenberg (Ref. 3) undertook a study to determine the effect of nine commonly ingested beverages on gastric acid secretion in humans. Six healthy subjects were each studied on 11 separate days and in random order. Test substances were 3 types of soda water, 3 different brands of instant coffee, tea, milk, and beer. The control was water. The results were considered significantly different for each beverage versus the control ($p<0.05$). The authors stated that this study indicates that each of the beverages tested is a potent stimulus of gastric acid secretion regardless of its caffeine content. Studies by Cohen and Booth (Ref. 4) likewise demonstrated that Caffeine stimulates gastric acid secretion and reduces the competence of the lower esophageal sphincter in healthy subjects. Noting that caffeine is a potent stimulant of gastric secretion in man, Roth and Ivy (Ref. 7) conducted experiments to determine the synergistic effect of caffeine upon alcohol. They observed that the gastric secretory response to the combined action of alcohol plus caffeine was an average of 65.9 percent greater than the response produced when alcohol and caffeine were given separately. Further, the response to the combination of alcohol and caffeine was prolonged, lasting approximately 70 minutes longer than that of the individual ingredients.

The Advisory Review panel on OTC Sedative, Tranquilizer, and Sleep-aid Drug Products (Sleep-aid Panel) noted in its advance notice of proposed rulemaking for OTC nighttime sleep-aid, daytime sedative, and stimulant drug products (December 8, 1975, 40 FR 57292 at 57324 to 57325) that caffeine stimulates gastric secretion in man. While that Panel stated that normal doses of caffeine (i.e., 100 milligrams) did not seem to cause irritation of the gastrointestinal tract, the agency notes that the target population considered by that Panel in its assessment of the safety and effectiveness of caffeine as an OTC stimulant did not specifically include individuals that already had some degree of stomach or gastrointestinal irritation or upset due to overindulgence in alcohol and/or food. Further, the Sleep-aid Panel did not give any consideration to the safety of caffeine in

patients with already high levels of stomach acid.

In view of caffeine's documented effect in stimulating gastric secretions, the agency does not believe that combination products containing both caffeine, which stimulates hydrochloric acid secretion, and an antacid, which reduces the concentration of hydrochloric acid and treats the symptoms associated with high levels of hydrochloric acid, are rational. Therefore, the agency is reversing the Panel's Category I recommendation and is placing in Category II all combination products for the treatment of hangover that contain both an antacid ingredient and caffeine, a stimulant ingredient. The agency is not aware of any marketed OTC drug combination products, other than hangover remedies, that contain both stimulant and antacid ingredients.

In the tentative final monograph for OTC orally administered drug products for relief of symptoms associated with overindulgence in food and drink, published elsewhere in this issue of the **Federal Register**, FDA states its position on the establishment of a monograph for these drug products. Recognizing that there was considerable overlap in claims included in certain other rulemakings and the rulemaking for drug products for relief of symptoms associated with overindulgence in food and drink and with hangover, the agency determined that those claims should be included in the appropriate monographs for antacid, internal analgesic, and stimulant drug products. The agency recognizes that combination products may be intended for use by a specific target population, such as consumers who are suffering from a hangover or overindulgence in food and drink. The agency believes that the labeling for such combination products should reflect the principal intended use(s) of the product (e.g., pain reliever, antacid, stimulant). Such labeling should be consistent with the approved indications for the active ingredients, but would not be required to contain all of the indications.

The agency believes that labeling specific to internal analgesic/antacid or internal analgesic/stimulant combinations need only appear in one monograph, with an appropriate cross-reference in the other monograph. The agency previously proposed a number of internal analgesic/antacid combinations in the internal analgesic tentative final monograph. (See § 343.20 (b)(1) and (b)(3) (November 16, 1988, 53 FR 46204 at 46255)). Concurrently, in the same issue of the **Federal Register** (53 FR 46190), the agency proposed to amend the final monograph for OTC antacid drug products to revise § 331.15(b) to include the combinations that were proposed in § 343.20 (b)(1) and (b)(3) of the internal analgesic tentative final monograph. Likewise, the agency proposed to add a new § 331.60 (entitled "*Labeling of permitted combinations of active ingredients*") to reflect that the new combinations included in § 331.15 (b)(1) and (b)(2) should use the indications proposed in § 343.60 (b)(2) and (b)(4), respectively, of the internal analgesic tentative final monograph.

In this current notice, the agency is proposing to amend the final monograph for OTC antacid drug products to add a claim for relief of upset stomach due to overindulgence in food and drink. The agency does not need to propose any amendment to the final monograph to address the Panel's recommendation concerning sodium citrate in solution for use in the relief of upset stomach associated with overindulgence in the combination of alcohol and food because citrate-containing active ingredients are already included in § 331.11(e) of the antacid monograph.

FDA has previously amended the final monograph for OTC antacid drug products to permit the labeling for these products to include a claim for the relief of upset stomach associated with heartburn, sour stomach, and/or acid indigestion (47 FR 38481). This amendment was based on data (that were discussed in the September 21, 1979, proposal to amend the antacid monograph (44 FR 54731 at 54732)) which demonstrated that the term "upset stomach" is often used by consumers to describe the symptoms "acid indigestion," "sour stomach," and "heartburn." The agency also recognized that a cluster of symptoms referred to as "upset stomach" may be caused by overindulgence in food and drink, but this use was not considered in the August 31, 1982, amendment to the antacid final monograph. At that time, the agency concluded that a symptom described simply as "upset stomach" would not be used as an indication for OTC antacid drug products because it had not been specifically demonstrated to be associated with gastric hyperacidity (47 FR 38481 at 38482). In reaching that conclusion, the agency failed to note that the Advisory Review Panel on OTC Antacid Drug Products (Antacid Panel) had pointed out that evidence of the association between hyperacidity and the Category I antacid indications "heartburn," "sour stomach," and "acid indigestion," is "far from conclusive" (April 5, 1973, 38 FR 8714 at 8720).

Because of a recognized association between upset stomach and overindulgence in food and drink, the agency stated that it had referred further consideration of this issue to the Miscellaneous Internal panel for review (47 FR 38481 at 38483). That Panel reviewed data on only one antacid ingredient (sodium citrate in solution) for overindulgence claims and concluded that the ingredient was effective in relieving "upset stomach" due to overindulgence in the combination of food and drink (47 FR 43540 at 43549 and 43550).

Based on the Miscellaneous Internal Panel's review, the data discussed in the September 21, 1979, proposal to amend the antacid monograph (47 FR 38481), and the Antacid Panel's conclusion regarding hyperacidity (38 FR 8714 at 8722), the agency believes that consumers perceive the term "upset stomach" to refer to a variety of symptoms properly treated with antacids, including symptoms of heartburn, sour stomach, and "upset stomach" symptoms which may be due to overindulgence in food and drink.

Based on the above findings, the agency is proposing to amend the indications in § 331.30(b) of the final monograph for OTC antacid drug products to provide that the phrase "and upset stomach associated with" may be followed by the phrase "overindulgence in food and drink." Because the Miscellaneous Internal Panel also recommended an antacid/analgesic combination for the relief of symptoms of overindulgence in food and drink, the agency is proposing to include this same option in the OTC internal analgesic tentative final monograph, published elsewhere in this issue of the **Federal Register**. Because of the interrelationship of this amendment to the antacid final monograph and to other proposals published elsewhere in this issue of the **Federal Register** to amend the tentative final monograph for OTC internal analgesic, antipyretic, and antirheumatic drug products and the final monograph for OTC stimulant drug products, the agency does not intend to finalize this amendment until the comments to all of the proposals have been fully evaluated.

References

(1) Rall, T. W., "Drugs Used in the Treatment of Asthma," in "The Pharmacological Basis of Therapeutics," 8th ed., edited by A. G. Gilman, et al., Pergamon Press, New York, p. 623, 1990.

(2) Ivey, K. J., and J. L. A. Roth, "Drug and Chemical-Induced Injuries of the Stomach," Chapter 64 in "Bockus Gastroenterology," 4th

ed., Edited by J. E. Berk, W. B. Saunders Co., Philadelphia, pp. 975 and 995, 1985.

(3) McArthur, K., D. Hogan, and J. I. Isenberg, "Relative Stimulatory Effects of Commonly Ingested Beverages on Gastric Acid Secretion in Humans," Gastroenterology, 83:199–203, 1982.

(4) Cohen, S., and G. H. Booth, Jr., "Gastric Acid Secretion and Lower-Esophageal-Sphincter Pressure in Response to Coffee and Caffeine," The New England Journal of Medicine, 293:897–899, 1975.

(5) Friedman, G. D., A. B. Siegelaub, and C. C. Seltzer, "Cigarettes, Alcohol, Coffee and Peptic Ulcer," The New England Journal of Medicine, 290:469–473, 1974.

(6) Debas, H. T., et al, "Caffeine-Stimulated Acid and Pepsin Secretion: Dose-Response Studies," Scandinavian Journal of Gastroenterology, 6:453–457, 1971.

(7) Roth, J. A., and A. C. Ivy, "The Synergistic Effect of Caffeine Upon Histamine in Relation to Gastric Secretion," American Journal of Physiology, 142:107–133, 1944.

The agency has examined the economic consequences of this proposed rulemaking in conjunction with other rules resulting from the OTC drug review. In a notice published in the **Federal Register** of February 8, 1983 (48 FR 5806), the agency announced the availability of an assessment of these economic impacts. The assessment determined that the combined impacts of all the rules resulting from the OTC drug review do not constitute a major rule according to the criteria established by Executive Order 12291. The agency therefore concludes that no one of these rules, including this proposed rule for OTC antacid drug products, is a major rule.

The economic assessment also concluded that the overall OTC drug review was not likely to have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act (Pub. L. 96–354). That assessment included a discretionary regulatory flexibility analysis in the event that an individual rule might impose an unusual or disproportionate impact on small entities. However, this particular rulemaking for OTC antacid drug products is not expected to pose such an impact on small businesses. Therefore, the agency certifies that this proposed rule, if implemented, will not have a significant economic impact on a substantial number of small entities.

The agency invites public comment regarding any substantial or significant economic impact that this rulemaking would have on OTC antacid drug products. Comments regarding the impact of this rulemaking on OTC antacid drug products should be accompanied by appropriate documentation.

The agency has determined under 21 CFR 25.24(c)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Interested persons may, on or before April 22, 1992, submit to the Docket Management Branch (address above), written comments or objections. Three copies of all comments or objections are to be submitted, except that individuals may submit one copy. Comments and objections are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Comments and objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 331

Labeling, Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 331 be amended to read as follows:

PART 331—ANTACID PRODUCTS FOR OVER-THE-COUNTER (OTC) HUMAN USE

1. The authority citation for 21 CFR part 331 continues to read as follows;

Authority: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371)

2. Section 331.30 is amended by revising paragraph (b) to read as follows:

§ 331.30 Labeling of antacid products.

* * * * *

(b) *Indications.* The labeling of the product states, under the heading "Indications," the following: "For the relief of" (select any or all of the following: "heartburn," "sour stomach," and/or "acid indigestion") (which may be followed by the statement: "and upset stomach associated with" (select one or more of the following, as appropriate "this symptom," "these symptoms," or "overindulgence in food and drink.")) Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in this paragraph, may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

* * * * *

Dated: November 1, 1991.

Michael R. Taylor,

Deputy Commissioner for Policy.

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federal register

Tuesday
December 24, 1991

Part V

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 340

Stimulant Drug Products for Over-the-Counter Human Use; Proposed Amendment to the Monograph; Notice of Proposed Rulemaking

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

21 CFR Part 340

[Docket No. 75N-244U]

RIN 0905-AA06

Stimulant Drug Products for Over-the-Counter Human Use; Proposed Amendment to the Monograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking to amend the final monograph for over-the-counter (OTC) stimulant drug products to include conditions for the relief of symptoms associated with hangover. FDA is issuing this notice of proposed rulemaking after considering the report and recommendations of the Advisory Review Panel on OTC Miscellaneous Internal Drug Products and public comments on the advance notice of proposed rulemaking for orally administered drug products for relief of symptoms associated with overindulgence in alcohol and food for OTC human use that was based on those recommendations. This proposal is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments, objections, or requests for oral hearing on the proposed regulation before the Commissioner of Food and Drugs by April 22, 1992. New data by December 24, 1992. Comments on the new data by February 24, 1992. Written comments on the agency's economic impact determination by April 22, 1992.

ADDRESSES: Written comments, objections, new data, or requests for oral hearing to the Dockets Management Branch (HFA-305), Food and Drug Administration, room 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 29, 1988 (53 FR 6100), FDA issued a final monograph for OTC stimulant drug products (21 CFR part 340). This monograph did not contain any provision for combination drug products containing stimulant and nonstimulant active ingredients.

In the **Federal Register** of October 1, 1982 (47 FR 43540), the Advisory Review Panel on OTC Miscellaneous Internal Drug Products (the Panel) reviewed data on drug products containing antacid, analgesic, and stimulant active ingredients in various combinations and recommended conditions for their safe and effective use in its report on orally administered drug products for the relief of symptoms associated with overindulgence in alcohol and food. That Panel concluded that combinations of Category I ingredients from the following pharmacologic groups were safe and effective for use in the relief of the symptoms of hangover: (1) Antacid and analgesic, (2) antacid and stimulant, (3) analgesic and stimulant, and (4) antacid, analgesic, and stimulant.

In the tentative final monograph for OTC drug products for the relief of symptoms associated with overindulgence in food and drink, published elsewhere in this issue of the **Federal Register**, FDA states for the first time its position on the establishment of a monograph for these drug products. In formulating its proposals on conditions for marketing combination products containing antacid, analgesic, and stimulant ingredients for the relief of symptoms associated with hangover and/or overindulgence in food and drink, the agency recognized that rulemaking significantly overlaps other rulemakings in the OTC drug review. For example, the Panel's recommendations on OTC drug products for the relief of hangover symptoms include a combination of ingredients already classified as Category I in the OTC antacid rulemaking (21 CFR part 331), the OTC stimulant rulemaking (21 CFR part 340), and the pending OTC internal analgesic, antipyretic, and antirheumatic rulemaking (21 CFR part 343), proposed in the **Federal Register** of November 16, 1988 (53 FR 46204). Therefore, the agency decided not to further consider ingredients for the relief of hangover symptoms in the overindulgence tentative final monograph and decided instead to amend the internal analgesic, antipyretic, and antirheumatic tentative final monograph, the antacid final monograph, and the stimulant final monograph to include a claim for the relief of symptoms of hangover for combinations of ingredients from these drug categories.

The agency notes, however, that in recommending combination products to treat hangover symptoms, the Panel failed to adequately consider that caffeine stimulates gastric secretion of hydrochloric acid (Refs. 1 through 7). The ability of caffeine to significantly increase hydrochloric acid secretion is mentioned in standard medical reference textbooks (Refs. 1 and 2) and was reported by Roth and Ivy (Ref. 7) as early as 1944. McArthur, Hogan, and Isenberg (Ref. 3) undertook a study to determine the effect of nine commonly ingested beverages on gastric acid secretion in humans. Six healthy subjects were each studied on 11 separate days and in random order. Test substances were 3 types of soda water, 3 different brands of instant coffee, tea, milk, and beer. The control was water. The results were considered significantly different for each beverage versus the control ($p<0.05$). The authors stated that this study indicates that each of the beverages tested is a potent stimulus of gastric acid secretion regardless of its caffeine content. Studies by Cohen and Booth (Ref. 4) likewise demonstrated that caffeine stimulates gastric acid secretion and reduces the competence of the lower esophageal sphincter in healthy subjects. Noting that caffeine is a potent stimulant of gastric secretion in man, Roth and Ivy (Ref. 7) conducted experiments to determine the synergistic effect of caffeine upon alcohol. They observed that the gastric secretory response to the combined action of alcohol plus caffeine was an average of 65.9 percent greater than the response produced when alcohol and caffeine were given separately. Further, the response to the combination of alcohol and caffeine was prolonged, lasting approximately 70 minutes longer than that of the individual ingredients.

The Advisory Review Panel on OTC Sedative, Tranquilizer, and Sleep-aid Drug Products (Sleep-aid Panel) noted in its advance notice of proposed rulemaking for OTC nighttime sleep-aid, daytime sedative, and stimulant drug products (December 8, 1975, 40 FR 57292 at 57324 to 57325) that caffeine stimulates gastric secretion in man. While that Panel stated that normal doses of caffeine (i.e., 100 milligrams) did not seem to cause irritation of the gastrointestinal tract, the agency notes that the target population considered by that Panel in its assessment of the safety and effectiveness of caffeine as an OTC stimulant did not specifically include individuals that already had some degree of stomach or gastrointestinal irritation or upset due to overindulgence in alcohol and/or food. Further, the Sleep-aid Panel did not give any consideration to the safety of caffeine in patients with already high levels of stomach acid.

In view of caffeine's documented effect in stimulating gastric secretions,

the agency does not believe that combination products containing both caffeine, which stimulates hydrochloric acid secretion, and an antacid, which reduces the concentration of hydrochloric acid and treats the symptoms associated with high levels of hydrochloric acid, are rational. Therefore, the agency is reversing the Panel's Category I recommendation and is placing in Category II all combination products for the treatment of hangover that contain both an antacid ingredient and caffeine, a stimulant ingredient. The agency is not aware of any marketed OTC drug combination products, other than hangover remedies, that contain both stimulant and antacid ingredients.

The agency believes that labeling specific to stimulant/internal analgesic combinations need only appear in one monograph, with an appropriate cross-reference in the other monograph. In this notice, the agency is proposing to add § 340.20 to the stimulant monograph to allow for the combination of caffeine, the stimulant active ingredient, with an internal analgesic ingredient. Such combinations are also being proposed in § 343.20(b)(5) of the internal analgesic monograph (21 CFR 343.20(b)(5)).

While the Miscellaneous Internal Panel recommended that any Category I stimulant ingredient could be combined with any Category I internal analgesic ingredient, the agency is not aware of a marketing history for combination products other than those containing a stimulant with acetaminophen or aspirin. Internal analgesic/stimulant combinations for the treatment of hangover are therefore being limited to the internal analgesic ingredients listed in § 343.10 (a) and (b)(1) only, i.e., acetaminophen and aspirin.

The agency is further proposing to add § 340.60 to provide for the labeling of combination drug products. For combinations containing a stimulant ingredient with an internal analgesic ingredient as provided for in § 340.20, the following indication should be used in addition to the appropriate indication related to the internal analgesic component "Helps restore mental alertness or wakefulness when experiencing fatigue or drowsiness associated with a hangover." Indications for such combinations are proposed in § 343.60(b)(6). In addition, § 340.60(c), the agency is proposing that the following warning be used for combination products containing a stimulant ingredient combined with any internal analgesic ingredient "For occasional use only. Do not use for more than 2 days for a hangover unless directed by a doctor. Not intended for use as a substitute for sleep. If fatigue or drowsiness persists or continues to recur, consult a doctor." This warning should be used instead of the warnings in §§ 340.50(c)(2) and 343.50(c)(1).

Because of the interrelationship of this amendment to the tentative final monograph for OTC internal analgesic, antipyretic, and antirheumatic drug products, the agency does not intend to finalize this amendment until the comments to the internal analgesic, antipyretic, and antirheumatic tentative final monograph have been fully evaluated.

References

(1) Rall, T. W., "Drugs Used in the Treatment of Asthma," *in* "The Pharmacological Basis of Therapeutics," 8th ed., edited by A. G. Gilman, et al., Pergamon Press, New York, p. 623, 1990.

(2) Ivey, K. J., and J. L. A. Roth, "Drug and Chemical-Induced Injuries of the Stomach," Chapter 64 *in* "Bockus Gastroenterology," 4th ed., Edited by J. E. Berk, W. B. Saunders Co., Philadelphia. pp. 975 and 995, 1985.

(3) McArthur, K., D. Hogan, and J. I. Isenberg, "Relative Stimulatory Effects of Commonly Ingested Beverages on Gastric Acid Secretion in Humans," Gastroenterology, 83:199–203, 1982.

(4) Cohen, S., and G. H. Booth, Jr., "Gastric Acid Secretion and Lower-Esophageal-Sphincter Pressure in Response to Coffee and Caffeine," The New England Journal of Medicine, 293:897–899, 1975.

(5) Friedman, G. D., A. B. Siegelaub, and C. C. Seltzer, "Cigarettes, Alcohol, Coffee and Peptic Ulcer," The New England Journal of Medicine, 290:469–473, 1974.

(6) Debas, H. T., et al., "Caffeine-Stimulated Acid and Pepsin Secretion: Dose-Response Studies," Scandinavian Journal of Gastroenterology, 6:453–457, 1971.

(7) Roth, J. A., and A. C. Ivy, "The Synergistic Effect of Caffeine Upon Histamine in Relation to Gastric Secretion," American Journal of Physiology, 142:107–113, 1944.

The agency has examined the economic consequences of this proposed rulemaking in conjunction with other rules resulting from the OTC drug review. In a notice published in the **Federal Register** of February 8, 1983 (48 FR 5806), the agency announced the availability of an assessment of these economic impacts. The assessment determined that the combined impacts of all the rules resulting from the OTC drug review do not constitute a major rule according to the criteria established by Executive Order 12291. The agency therefore concludes that not one of these rules, including this proposed rule for OTC stimulant drug products, is a major rule.

The economic assessment also concluded that the overall OTC drug review was not likely to have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act (Pub. L. 96–354). That assessment included a discretionary regulatory flexibility analysis in the event that an individual rule might impose an unusual or disproportionate impact on small entities. However, this particular rulemaking for OTC stimulant drug products is not expected to pose such an impact on small businesses. Therefore, the agency certifies that this proposed rule, if implemented, will not have a significant economic impact on a substantial number of small entities.

The agency invites public comment regarding any substantial or significant economic impact that this rulemaking would have on OTC stimulant drug products. Comments regarding the impact of this rulemaking on OTC stimulant drug products should be accompanied by appropriate documentation.

The agency has determined under 21 CFR 25.24(c)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Interested persons may, on or before April 22, 1992, submit to the Dockets Management Branch (address above), written comments or objections. Three copies of all comments or objections are to be submitted, except that individuals may submit one copy. Comments and objections are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Comments and objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 340

Labeling, over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 340 be amended as follows:

PART 340—STIMULANT DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR part 340 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371).

2. New § 340.20 is added to subpart B to read as follows:

§ 340.20 Permitted combinations of active ingredients.

The following combinations are permitted provided each active ingredient is present within the established dosage limits and the products is labeled in accordance with § 340.60.

(a) *Combinations containing a stimulant active ingredient and an internal analgesic active ingredient.* (See § 343.20(b)(5) of this chapter.)

(b) [Reserved]

3. New § 340.60 is added to Subpart C to read as follows:

§ 340.60 Labeling of permitted combinations of active ingredients.

Statements of identity, indications, warnings, and directions for use, respectively, applicable to each ingredient in the product may be combined to eliminate duplicative words or phrases so that the resulting information is clear and understandable.

(a) *Statement of identity.* For a combination drug product that has an established name, the labeling of the product states the established name of the combination drug product, followed by the statement of identity for each ingredient in the combination, as established in the statement of identity sections of the applicable over-the-counter (OTC) drug monographs. For a combination drug product that does not have an established name, the labeling of the product states the statement of identity for each ingredient in the combination, as established in the statement of identity sections of the applicable OTC drug monographs.

(b) *Indications.* The labeling of the product states, under the heading "Indications," the indication(s) for each ingredient in the combination, as established in the indications sections of the applicable OTC drug monographs, unless otherwise stated in this paragraph. Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in this paragraph may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the act Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) *For permitted combinations containing a stimulant and an internal analgesic active ingredient identified in § 340.20(a).* The indications in § 343.60(b)(6) of this chapter should be used.

(2) [Reserved]

(c) *Warnings.* The labeling of the product states, under the heading "Warnings," the warning(s) for each ingredient in the combination, as established in the warnings sections of the applicable OTC drug monographs, unless otherwise stated in this paragraph.

For permitted combinations containing any stimulant ingredient identified in § 340.20. The following warning should be used instead of the warnings in § § 340.50(c)(2) and 343.50(c)(1) of this chapter: "For occasional use only. Do not use for more than 2 days for a hangover unless directed by a doctor. Not intended for use as a substitute for sleep. If fatigue or drowsiness persists or continues to recur, consult a" (select one of the following: "physician" or "doctor").

(2) [Reserved]

(d) *Directions.* The labeling of the product states, under the heading "Directions," directions that conform to the directions established for each ingredient in the directions sections of the applicable OTC drug monographs, unless otherwise stated in this paragraph. When the time intervals or age limitations for administration of the individual ingredients differ, the directions for the combination product:

(1) May not contain any dosage that exceeds those established for any individual ingredient in the applicable OTC drug monograph(s), and

(2) May not provide for use by any age group lower than the highest minimum age limit establish for any individual ingredient.

Dated: November 1, 1991.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 91-30426 Filed 12-23-91; 8:45 am]

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federal register

Tuesday
December 24, 1991

Part VI

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 343

Internal Analgesic, Antipyretic, and Antirheumatic Drug Products For Over-The-Counter Human Use; Proposed Amendment to the Tentative Final Monograph; Notice of Proposed Rulemaking

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 343

[Docket No. 77N-094U]

RIN 0905-AA06

Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use; Proposed Amendment to the Tentative Final Monograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking to amend the tentative final monograph for over-the-counter (OTC) internal analgesic, antipyretic, and antirheumatic drug products to include conditions for the relief of upset stomach associated with overindulgence in food and drink and the relief of symptoms associated with hangover. FDA is issuing this notice of proposed rulemaking after considering the report and recommendations of the Advisory Review Panel on OTC Miscellaneous Internal Drug Products and public comments on the advance notice of proposed rulemaking for orally administered drug products for relief of symptoms associated with overindulgence in alcohol and food for OTC human use that was based on those recommendations. This proposal is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments, objections, or requests for oral hearings on the proposed regulation before the Commissioner of Food and Drugs by April 22, 1992. New data by December 24, 1992. Comments on the new data by February 24, 1993. Written comments on the agency's economic impact determination by April 22, 1992.

ADDRESSES: Written comments, objections, new data, or requests for oral hearing to the Dockets Management Branch (HFA-305), Food and Drug Administration, room 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 16, 1988 (53 FR 46204), FDA issued a tentative final monograph for OTC internal analgesic, antipyretic, and antirheumatic drug products (21 CFR Part 343). That proposal included conditions for marketing combination drug products containing internal analgesic and antacid ingredients. The agency proposed that (1) acetaminophen may be combined with any antacid ingredient(s) and may be labeled only for concurrent symptoms, and (2) aspirin may be combined with any antacid ingredient(s) when marketed in a form intended for ingestion as a solution and may be labeled for concurrent symptoms as well as analgesic indications alone. (See proposed § 343.20(b) (1) and (3) at 53 FR 46204 at 46255.)

As part of the rulemaking for orally administered drug products for relief of symptoms associated with overindulgence in alcohol and food for OTC human use, published in the **Federal Register** of October 1, 1982 (47 FR 43540), the Advisory Review Panel on OTC Miscellaneous Internal Drug Products (the Panel) reviewed data on drug products containing antacid, analgesic, and stimulant ingredients in various combinations and recommended conditions for their safe and effective OTC use. The Panel concluded that the following combinations of Category I ingredients were safe and effective for use in relief of the symptoms of hangover: (1) Antacids and analgesics, (2) antacids and stimulants, (3) analgesics and stimulants, and (4) antacids, analgesics, and stimulants. The Panel also recommended that the antacid ingredient sodium citrate in solution could be combined with any Category I internal analgesic ingredient and be labeled for the relief of symptoms of upset stomach associated with overindulgence in the combination of alcohol and food. The Panel added that if the product contains aspirin (as identified in Part 343), the finished product must meet the acid neutralizing requirements of § 331.10 of the antacid monograph (21 CFR 331.10).

In the tentative final monograph for OTC orally administered drug products for relief of symptoms associated with overindulgence in food and drink, published elsewhere in this issue of the **Federal Register**, FDA states its position on the establishment of a monograph for these drug products. Recognizing that there was considerable overlap in claims included in certain other rulemakings and the rulemaking for drug products for relief of symptoms associated with overindulgence in food and drink and with hangover, the agency determined that those claims should be included in the appropriate monographs for OTC antacid, internal analgesic, and stimulant drug products. The agency recognizes that combination products may be intended for use by a specific target population, such as consumers who are suffering from a hangover or from overindulgence in food and drink. The agency believes that the labeling for such combination products should reflect the principal intended use(s) of the product (e.g., pain reliever, antacid, stimulant). Such labeling should be consistent with the approved indications for the active ingredients, but would not be required to contain all of the indications.

The agency notes, however, that in recommending combination products to treat hangover symptoms, the Panel failed to adequately consider that caffeine stimulates gastric secretion of hydrochloric acid (Refs. 1 through 7). The ability of caffeine to significantly increase hydrochloric acid secretion is mentioned in standard medical reference textbooks (Refs. 1 and 2) and was reported by Roth and Ivy (Ref. 7) as early as 1944. McArthur, Hogan, and Isenberg (Ref. 3) undertook a study to determine the effect of nine commonly ingested beverages on gastric acid secretion in humans. Six healthy subjects were each studied on 11 separate days and in random order. Test substances were 3 types of soda water, 3 different brands of instant coffee, tea, milk, and beer. The control was water. The results were considered significantly different for each beverage versus the control ($p < 0.05$). The authors stated that this study indicates that each of the beverages tested is a potent stimulus of gastric acid secretion regardless of its caffeine content. Studies by Cohen and Booth (Ref. 4) likewise demonstrated that caffeine stimulates gastric acid secretion and reduces the competence of the lower esophageal sphincter in healthy subjects. Noting that caffeine is a potent stimulant of gastric secretion in man, Roth and Ivy, (Ref. 7) conducted experiments to determine the synergistic effect of caffeine upon alcohol. They observed that the gastric secretory response to the combined action of alcohol plus caffeine was an average of 65.9 percent greater than the response produced when alcohol and caffeine were given separately. Further, the response to the combination of alcohol and caffeine was prolonged, lasting approximately 70 minutes longer than that of the individual ingredients.

The Advisory Review Panel on OTC Sedative, Tranquilizer, and Sleep-aid Drug Products (Sleep-aid Panel) noted in its advance notice of proposed rulemaking for OTC nighttime sleep-aid, daytime sedative, and stimulant drug

products (December 8, 1975, 40 FR 57292 at 57324 to 57325) that caffeine stimulates gastric secretion in man. While that Panel stated that normal doses of caffeine (i.e., 100 milligrams) did not seem to cause irritation of the gastrointestinal tract, the agency notes that the target population considered by that Panel in its assessment of the safety and effectiveness of caffeine as an OTC stimulant did not specifically include individuals that already has some degree of stomach or gastrointestinal irritation or upset due to overindulgence in alcohol and/or food. Further, the Sleep-aid Panel did not give any consideration to the safety of caffeine in patients with already high levels of stomach acid.

In view of caffeine's documented effect in stimulating gastric secretions, the agency does not believe that combination products containing both caffeine, which stimulates hydrochloric acid secretion, and an antacid, which reduces the concentration of hydrochloric acid and treats the symptoms associated with high levels of hydrochloric acid, are rational. Similarly, combination drug products containing internal analgesic, antacid, and stimulant ingredients are also irrational. Therefore, the agency is reversing the Panel's Category I recommendation and is placing in Category II all combination products for the treatment of hangover that contain both an antacid ingredient and caffeine, a stimulant ingredient. The agency is not aware of any marketed OTC drug combination products, other than hangover remedies, that contain both stimulant and antacid ingredients, plus an internal analgesic.

The agency believes that labeling specific to internal analgesic/antacid or internal analgesic/stimulant combinations need only appear in one monograph, with an appropriate cross-reference in the other monograph. A number of internal analgesic/antacid combinations were proposed in the internal analgesic tentative final monograph. (See § 343.20(b) (1) and (3) (53 FR 46204 at 46255).) Concurrently, in the same issue of the **Federal Register** (November 16, 1988, 53 FR 46190), the agency proposed to amend the final monograph for OTC antacid drug products to revise § 331.15(b) to include the combinations that were proposed in § 343.20(b) (1) and (3) of the internal analgesic tentative final monograph. Likewise, the agency proposed to add a new § 331.60 (entitled "*Labeling of permitted combinations of active ingredients*") to reflect that the new combinations included in § 331.15 (b)(1) and (b)(2) should use the indications proposed in § 343.60 (b)(2) and (b)(4), respectively, of the internal analgesic tentative final monograph.

In this current notice, the agency is proposing to add new § 343.20(b)(5) to allow for internal analgesic and stimulant combination drug products. While the Miscellaneous Internal Panel recommended that any Category I stimulant ingredient could be combined with any Category I internal analgesic ingredient, the agency is not aware of a marketing history for combination products other than those containing a stimulant with aspirin or acetaminophen. Internal analgesic/stimulant combinations for the treatment of hangover are, therefore, being limited to the internal analgesic ingredients listed in § 343.10 (a) and (b)(1) only, i.e., acetaminophen and aspirin.

This notice also amends the labeling for internal analgesic/antacid combinations proposed in § 343.60 (b)(2) and (b)(4) of the OTC internal analgesic, antipyretic, and antirheumatic tentative final monograph to include a claim for relief or symptoms of hangover and a claim for relief of symptoms of overindulgence in food and drink. Because of the interrelationship of this amendment to the internal analgesic, antipyretic, and antirheumatic tentative final monograph and to other proposals included elsewhere in this issue of the **Federal Register** to amended the final monograph for OTC antacid drug products and the final monograph for OTC stimulant drug products, the agency does not intend to finalize this amendment until the comments to all of these proposals have been fully evaluated.

In this notice, the agency is also proposing to add new § 343.60(c)(1) containing the following warning for internal analgesic/antacid combination products labeled for the relief of symptoms of hangover, "Do not use for more than 2 days for a hangover unless directed by a doctor." This warning is being added because, although hangover is generally an acute self-limiting condition, the symptom complex can be experienced for periods of several days, either as a result of excessive and physically harmful consumption of alcoholic beverages or as a result of the consumption of alcohol aggravating some other disease or condition. If symptoms persist for more than 2 days, the individual should seek medical guidance and not continue to rely on a hangover remedy for symptomatic relief.

The agency is further proposing to revise the labeling directions for combination drug products in § 343.60(d), by modifying the last sentence as follows:

* * * the directions for the combination product:

(1) May not contain any dosage that exceeds those established for any individual ingredient in the applicable OTC drug monograph(s), and

(2) May not provide for use by any age group lower than the highest minimum age limit established for any individual ingredient.

This change is being made to make these labeling directions for combination drug products consistent with other recently proposed OTC drug monographs.

References

(1) Rall, T.W., "Drugs Used in the Treatment of Asthma," in "The Pharmacological Basis of Therapeutics," 8th ed., edited by A.G. Gilman, et al., Pergamon Press, New York, p. 623, 1990.

(2) Ivey, K.J., and J.L.A. Roth, "Drug and Chemical-Induced Injuries of the Stomach," Chapter 64 in "Bockus Gastroenterology," 4th ed., Edited by J.E. Berk, W.B. Saunders Co., Philadelphia, pp. 975 and 995, 1985.

(3) McArthur, K., D. Hogan, and J.I. Isenberg, "Relative Stimulatory Effects of Commonly Ingested Beverages on Gastric Acid Secretion in Humans," Gastroenterology, 83:199–203, 1982.

(4) Cohen, S., and G.H. Booth, Jr., "Gastric Acid Secretion and Lower-Esophageal-Sphincter Pressure in Response to Coffee and Caffeine," The New England Journal of Medicine, 293:897–899, 1975.

(5) Friedman, G.D., A.B. Siegelaub, and C.C. Seltzer, "Cigarettes, Alcohol, Coffee and Peptic Ulcer," The New England Journal of Medicine, 290:469–473, 1974.

(6) Debas, H.T., et al., "Caffeine-Stimulated Acid and Pepsin Secretion: Dose-Response Studies," Scandinavian Journal of Gastroenterology, 6:453–457, 1971.

(7) Roth, J.A., and A.C. Ivy, "The Synergistic Effect of Caffeine Upon Histamine in Relation to Gastric Secretion," American Journal of Physiology, 142:107–113, 1944.

The agency has examined the economic consequences of this proposed rulemaking in conjunction with other rules resulting from the OTC drug review. In a notice published in the **Federal Register** of February 8, 1983 (48 FR 5806), the agency announced the availability of an assessment of these economic impacts. The assessment determined that the combined impacts of all the rules resulting from the OTC drug review do not constitute a major rule according to the criteria established by Executive Order 12291. The agency therefore concludes that no one of these rules, including this proposed rule for OTC internal analgesic, antipyretic, and

antirheumatic drug products, is a major rule.

The economic assessment also concluded that the overall OTC drug review was not likely to have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act (Pub. L. 96–354). That assessment included a discretionary regulatory flexibility analysis in the event that an individual rule might impose an unusual or disproportionate impact on small entities. However, this particular rulemaking for OTC internal analgesic, antipyretic, and antirheumatic drug products is not expected to pose such an impact on small businesses. Therefore, the agency certifies that this proposed rule, if implemented, will not have a significant economic impact on a substantial number of small entities.

The agency invites public comment regarding any substantial or significant economic impact that this rulemaking would have on OTC internal analgesic, antipyretic, and antirheumatic drug products. Comments regarding the impact of this rulemaking on OTC internal analgesic, antipyretic, and antirheumatic drug products should be accompanied by appropriate documentation.

The agency has determined under 21 CFR 25.24(c)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Interested persons may, on or before April 22, 1992, submit to the Dockets Management Branch (address above), written comments or objections. Three copies of all comments or objections are to be submitted, except that individuals may submit one copy. Comments and objections are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Comments and objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 343

Internal analgesic drug products, Labeling, Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 343, as proposed in the **Federal Register** of November 16, 1988 (53 FR 46204), be amended as follows:

PART 343—INTERNAL ANALGESIC, ANTIPYRETIC, AND ANTIRHEUMATIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation in 21 CFR part 343 is revised to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 701 (21 U.S.C. 321, 351, 352, 353, 355, 360, 371).

2. Section 343.20 is amended by adding new paragraph (b)(5) to read as follows:

§ 343.20 Permitted combinations of active ingredients.

* * * * *

(b) * * *

(5) *Internal analgesic and stimulant combinations.* Any internal analgesic ingredient identified in § 343.10 (a) or (b)(1) of this chapter may be combined with any stimulant ingredient identified in § 340.10 of this chapter provided the product bears labeling indications in accordance with § 343.60(b)(6).

3. Section 343.60 is amended by revising paragraphs (b)(2), (b)(4), (c), and (d), and by adding new paragraph (b)(6) to read as follows:

§ 343.60 Labeling of permitted combinations of active ingredients.

* * * * *

(b) * * *

(2) *For permitted combinations identified in § 343.20(b)(1).* The indications are the following: "For the temporary relief of minor aches and pains with" (select one or more of the following: "heartburn," "sour stomach," or "acid indigestion") (which may be followed by: "and upset stomach associated with" (select one or more of the following, as appropriate: "this symptom," "these symptoms," "hangover," or "overindulgence in food and drink.")]

* * * * *

(4) *For permitted combinations identified in § 343.20(b)(3).* The indications are the following: "For the temporary relief of minor aches and pains with" (select one or more of the following: "heartburn," "sour stomach," or "acid indigestion") [which may be followed by "and upset stomach associated with" (select one or more of the following, as appropriate: "this symptom," "these symptoms," "hangover," or "overindulgence in food and drink")] and "Also may be used for the temporary relief of minor aches and pains alone" [which may be followed by one or more of the following: ("such as associated with" (select one or more of the following: "a cold," "the common cold," "sore throat," "headache," "toothache," "muscular aches," "backache," "the premenstrual and menstrual periods" (which may be followed by "(dysmenorrhea)"), or "premenstrual and menstrual cramps" (which may be followed by: "(dysmenorrhea)")], ("and for the minor pain from arthritis"), and ("and to reduce fever.")]

* * * * *

(6) *For permitted combinations identified in § 343.20(b)(5).* The indications are the following: "For the temporary relief of minor aches and pain associated with a hangover. Helps restore mental alertness or wakefulness when experiencing fatigue or drowsiness associated with a hangover."

* * * * *

(c) *Warnings.* The labeling of the product states, under the heading "Warnings," the warning(s) for each ingredient in the combination, as established in the warnings sections of the applicable OTC drug monographs, unless otherwise stated in this paragraph.

(1) *For permitted combinations identified in § 343.20 (b)(1) and (b)(3) when labeled for the relief of the symptoms of hangover.* "Do not use for more than 2 days for a hangover unless directed by a doctor."

(2) [Reserved]

(d) *Directions.* The labeling of the product states, under the heading "Directions," directions that conform to the directions established for each ingredient in the directions sections of the applicable OTC drug monographs, unless otherwise stated in this paragraph. When the time intervals or age limitations for administration of the individual ingredients differ, the directions for the combination product:

(1) May not contain any dosage that exceeds those established for any individual ingredient in the applicable OTC drug monograph(s), and

(2) May not provide for use by any age group lower than the highest minimum age limit established for any individual ingredient.

Dated: November 1, 1991.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 91–30424 Filed 12–23–91; 8:45 am]

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federal register

Tuesday
December 24, 1991

Part VII

Department of Transportation

Coast Guard

33 CFR Part 143
46 CFR Part 2
Direct User Fees for Inspection or Examination of U.S. and Foreign Commercial Vessels; Proposed Rule; Correction

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 143

46 CFR Part 2

[CGD 91-030]

RIN 2115-AD78

Direct User Fees for Inspection or Examination of U.S. and Foreign Commercial Vessels

AGENCY: Coast Guard, DOT.

ACTION: Notice of proposed rulemaking; correction.

SUMMARY: On December 18, 1991, the Coast Guard published a notice of proposed rulemaking (56 FR 65786). Appendix A to that rulemaking was omitted from publication. This correction document publishes appendix A to the notice of proposed rulemaking.

FOR FURTHER INFORMATION CONTACT: Commander Bruce A. Russell, Plans and Analysis Branch (G–MP–1), Office of Marine Safety, Security and Environmental Protection (202) 267–6923.

SUPPLEMENTARY INFORMATION: To assist the reader in understanding the basis for the user fees proposed in this rulemaking the Coast Guard has attached a summary of the preliminary regulatory evaluation, including the regulatory flexibility analysis, prepared for this rulemaking project. The summary is published as an appendix to the preamble to this notice of proposed rulemaking and will not be republished in the final rule. The complete preliminary regulatory evaluation is available in the rulemaking docket for inspection or copying.

This document adds Appendix A that was inadvertently omitted from the notice of proposed rulemaking. All other provisions of the notice of proposed rulemaking remain unchanged.

Corrections: On page 65796, add appendix A to read as follows:

Dated: December 19, 1991.

A.F. Bridgman, Jr.,

U.S. Coast Guard, Chief, Regulations and Administrative Law Division.

APPENDIX

Summary of Preliminary Regulatory Evaluation and Regulatory Flexibility Analysis of the Regulations to Implement Direct User Fees for Inspection or Examination of U.S. and Foreign Commercial Vessels

I. Introduction

A cost-benefit analysis was not prepared for this evaluation. Since the regulatory proposal is a deficit-reduction measure of the Budget Reconciliation Act of 1990 (the Act), there will be no benefits to the segment of the public affected by this proposal. However, the regulatory proposal will have an impact on many companies. Vessel inspections and examinations have previously been provided free of charge by the Coast Guard, so any fee for such services will have an impact, no matter how small. This analysis will describe the methodology used by the Coast Guard to develop a fee structure for vessel inspections and examinations and the impact of this fee structure on vessel owners.

II. Derivation of Vessel Inspection User Fees

These fees were derived based on the proposition that U.S. and foreign commercial vessel inspections and examinations should generate revenues approximating the total costs of the commercial vessel inspection program *less* costs for: Activities which will be the subject of separate rulemakings (i.e., new construction inspections, plan review, construction oversight, equipment approval and factory inspections); activities for which the program director has determined that the imposition of user fees would be administratively burdensome to both the Coast Guard and the marine industry; and, inspection activity costs in excess of the statutory annual user fee cap of $500 for the inspection of tank barges. The section of this paper titled Program Costs for Vessel Inspection User Fees details the program costs and reductions.

Program costs were derived using inspection activity data from the Coast Guard's Marine Safety Information System (MSIS), a 1989 "M" (Office of Marine Safety, Security and Environmental Protection) workload survey, data on MSIS costs, and field travel costs (automobile mileage).

The MSIS data used covered one-year periods during 1987, 1988, and 1989–90. Workloads vary from year to year as a function of regional, national and international industry trends. However, workload per unit of inspection activity (mean inspector hours per inspection), as a function of inspection activity and vessel type or service were found to be consistent over time.

The cost of the vessel inspection program subject to this rulemaking was computed in accordance with the Coast Guard Staffing Standards Manual (COMDTINST 5312.11) and the Standard Rate Instruction (COMDTINST 7310.1). The total was determined to be approximately $25.4–$27.0M, excluding collection costs. The accounting is detailed in the section titled Program Cost for Vessel Inspection User Fees. Enforcement boardings of uninspected vessels, U.S. commercial vessels, and foreign vessels have been excluded from the program cost model, and will not be the subject of a user fee rulemaking. New construction activities, factory inspections, equipment approvals, and plan review have also been excluded from the program cost model, but will be covered by separate user fee rulemakings.

Following the determination of program costs and available inspection hours, the Coast Guard derived the basic hourly rate. This rate distributes the program cost among identifiable inspection activities. The calculation of the basis hourly rate is detailed in the section titled Billable Hourly Rate Calculation. Each annual user fee is computed as a function of the time the Coast Guard would reasonably expect to spend inspecting or examining a specific category of vessel during an average year. All other fees for examination or inspection of vessels were based on the mean inspection or examination time for the specific type of inspection.

This project proposes to assess approximately $21–22 million in annual user fees, out of the $25.4–$27.0M program cost. A limitation in the Act, which set a maximum allowable annual user fee for inspection of tank barges ($500), reduces estimated receipts by approximately $2.1 million annually. This amount was eliminated from the cost model to ensure that the costs would not be included in the overhead and charged to the remaining industry. To simplify the fee structure and minimize the impact of the fee assessment and collection system on both the marine industry and the Coast Guard, several adjustments were introduced which reduce annual collections estimates by approximately $3.2 million. In each instance where decisions were made to not assess a user fee, to assess less than the full cost of performing the inspections, or where the fee will be collected under a separate rule, the Coast Guard was careful to exclude overhead costs as well as the cost of the activity. These costs, therefore, were not inadvertently distributed to activities subject to user fees.

Program Cost for Vessel Inspection User Fees

The Coast Guard attributes approximately 416 inspector full time equivalents (FTE) at field units to that

portion of the vessel inspection program subject to this rulemaking. Field personnel program cost was determined using the Standard Rate Instruction COMDTINST 7310.1, which establishes a base hourly rate (salary cost) of $30/hour (unspecified average officer):

416 × 1738 hrs. × $30 × 1.29 = $28,050,000

In addition to personnel costs, two other extraordinary costs accrue to the vessel inspection program: Marine Safety Information Systems (MSIS) costs and automobile mileage costs.

(1) MSIS Costs: $3,100,000 annual contract.

Inspection program prorated share: 12.5% or $389,000.

(2) Automobile mileage: 1,598,795 miles/year (1988 summary).

Cost/mile: $.24.

Inspection program prorated share: 89.5% or $343,000.

Therefore the total cost of the vessel inspection program is estimated to be:

Personnel	$28,050,000
MSIS	389,000
Auto mileage	343,000
	$28,782,000

Billable Hourly Rate Calculation

Total annual vessel inspection hours, (not including training hours, uninspected vessels or factory inspections but including new construction and plan review), for the most recently available 12 month period June 1989–June 1990, was 330,891 hours.

Therefore, the billable hourly rate was determined to be: $28,782,000/330,891 hours = $87/hour.

Cost Deferred to Other Rulemakings

The Coast Guard has determined that plan review and new construction inspections will not be the subject of this rulemaking. These costs are included in the gross vessel inspection program cost. The Coast Guard had not yet developed a satisfactory scheme to assess user fees for these activities in an equitable and administratively simple manner. Fees for these activities will be the subject of separate rulemakings. Because of the annual variability in new construction activities, the Coast Guard can only estimate that these activities could generate $1.8–3.3 million in annual user fee receipts (20,000–38,000 inspection hours at $87/hour).

Fee Reductions

Follow-on Inspections. For administrative simplicity and because of the wide range of variability within each type of follow-on inspection, only 50% of the expected value of most follow on inspections were included in the annual fee. While some vessel owners will receive more services than they pay for under this reduction, it minimizes the probability that those owners requiring the minimum of inspection services will have to pay a share of the cost of the high-end users.

Annual Reduction: $1,930,000.

Inspection intervals for hull examinations change as the vessel's service or route changes (e.g., salt water/fresh water). We have elected to avoid the potential for additional administrative and political disputes by charging only for the longest inspection interval (and lowest cost) for each type of vessel.

Annual Reduction: $948,000.

Tank Barges. Inspection User fees for all tank barges (U.S. and foreign) are limited to a maximum of $500 per year by the Budget Reconciliation Act of 1990. Annual user fees for tank barges would exceed $500 ($778–$1015 not including collection costs). Savings to the tank barge industry because of this statutorily-mandated provision are estimated at $2.1 million annually.

Annual Reduction: $2,087,000.

Foreign Passenger Vessels. Inspection times for approximately 5% of foreign passenger vessels exceed the normal range significantly, some as much as 40 times the mean inspection time. This disparity, which may result from unusual design, age, or poor maintenance, is expected to become more common as more vessels enter the U.S. cruise market. Until the causes for this disparity can be better defined and categorized, the excess inspection hours will be provided with no charge above the standard fee.

Annual Reduction: $109,000.

Miscellaneous: Passenger Freight Permit, Personnel in Addition to Crew Permit, and noncredit drydock inspection fees are not proposed since these services are usually provided only to the 20 Nautical School ships. The fees would be administratively burdensome and would not generate sufficient revenue to justify the burden.

Annual Reduction: $46,000.

Recapitulation

The following is a recapitulation of vessel inspection program costs, fee reductions, and estimated user fee receipts:

[In dollars]

Gross Vessel Inspections Cost.	28,782,000
Less New Construction/Plan Review.	(1.8M–3.3M)
Net Vessel Inspections Cost..	25.5–27.0
Less Fee reductions	5,120,000
Theoretical Receipts	20.4–21.9M
Estimated user fee receipts based on calculated fees, fleet and other activities.	21.0M

Fee Development

Initially the Coast Guard expected to charge a user fee for each inspection conducted. Fifteen types of inspection and 28 vessel categories were defined. Using these, the Coast Guard could establish 420 different user fees for the over 38,000 annual inspections.

The Coast Guard proceeded from this point to reduce the number of fee categories by looking for patterns in the amount of time it takes to conduct an inspection by inspection type, vessel type, and other factors. Because of the wide variation in the time to inspect each vessel it was suggested that the Coast Guard charge an hourly user fee after the exam was completed. This was rejected as unworkable. The cost of billing, timekeeping and administration would be enormous.

The Coast Guard is proposing one annual fee for each type of vessel. The fee would include follow-on inspections via an annual accrual accounting system based on the annual expected value of inspection services provided. Each user fee was annualized, and computed as a function of the time the Coast Guard would reasonably expect to spend on average examining a specific category of vessel during the course of an average year. This was done to minimize administrative burden, reduce collection costs, and provide a predictable cost to vessel owners. Table 2.10–3 in the proposed rule shows the annual fees for each type of inspected vessel.

Opportunity for Prepaying Fee

Vessel owners are being given the opportunity to prepay their annual user fee up to the remaining life of the vessel. The prepayment fee will be calculated as the net present value of the expected series of annual payments to the Treasury, adjusted for inflation and discounted at a rate equal to the interest rate for ten-year Treasury notes. This fee, once paid, will be transferable to the next owner. This is an optional procedure. The advantage of this is that the vessel owner is able to predict the costs of this item for 10–20 years. This can be important when developing budget estimates for capital

improvements. The prepayment formula is published in § 2.10–4 of the proposed rule.

Fees That Differ From the Standard Formula Tank Barge User Fee Limit

The Act capped user fees for inspection of non-self-propelled tank vessels (tank barges) at $500 for both foreign and domestic vessels. The Coast Guard determined the annual expected cost of inspecting tank barges, excluding collection costs, to be $778–$1,015. The Coast Guard therefore established the fee for tank barges at $500. The savings to the tank barge industry is estimated to be $2.1 million annually or approximately $500 per vessel each year (see Table I).

Excursion Permit Inspection Fee

An "excursion vessel" referred to in 46 CFR 2.01–45, 72.40–5(c), and 177.35–1(c), is a passenger vessel that engages in short cruises for special events or recreational purposes. Operation under an excursion permit is chiefly seasonal and normally involves the carriage of deck passengers. The excursion permit allows carrying excursion passengers in excess of the number permitted under a normal certificate of inspection, operation on an extended route, or permits another type of vessel to carry passengers. This is a temporary permit only, and the fee is to be paid upon application for the inspection. The excursion permit user fee is $424. Only 35 excursion permits were issued in 1989. The institution of this fee may eliminate requests for some excursion permits. Excursion permits are issued so infrequently it should have little or no impact on industry or the general public.

Overseas Inspection User Fee

An estimated 40,000 hours in overseas travel time are expended annually in connection with inspection of U.S. commercial vessels. These inspections are conducted at the request of the vessel owner. Owners now reimburse the Coast Guard (under 46 U.S.C. 3317) for actual travel expenses and per-diem, but not for additional operating costs associated with overseas inspections. Personnel hours expended during travel and costs for the operation of overseas offices are included among the costs which require a differential fee for these inspections. This fee would be an additional $4,586 per overseas inspection.

Foreign Tank Ship User Fee

Foreign chemical tank ships operating in U.S. waters must be examined and issued a Certificate of Compliance (COC). The COC is valid for two years, but the vessel must be reexamined annually by a marine inspector. Foreign tank ships carrying petroleum products are issued an annual Tank Vessel Examination (TVE) letter. As the time involved to conduct these exams is essentially the same, the Coast Guard proposes to charge the same fee for these examinations and reexaminations, $1,102.

Foreign Mobile Offshore Drilling Unit (MODU) User Fee

Foreign MODU's operating in U.S. waters are required to be inspected and obtain a Certificate of Compliance valid for one year or until the MODU departs the Outer Continental Shelf (OCS) whichever comes first. The fee for these inspections is $1,831.

Foreign Passenger Vessel Control Verification User Fee

Over 95% of foreign passenger vessel control verification examinations are straightforward, conducted on a regular basis, and are predictable in terms of inspection time spent per examination. A fixed fee which would be applicable to the initial, annual and reinspection examination is being proposed. For the remaining 5%, inspection times are as much as 40 times the mean. The Coast Guard proposes to charge these vessels the same fee as the 95% which require no significant extra effort. This fee is $1,047 and is paid on application for the inspection. Since these examinations are conducted quarterly when the vessels are operating from U.S. ports, the cost to the owner could be as much as $4,188 annually.

III. Impact

The annual cost of the proposed vessel inspection user fees is estimated to be $21–22 million. The hourly cost of a Coast Guard inspection is $87. This compares favorably with the inspection fee charged by American Bureau of Shipping (ABS) which is estimated at $95–$100 per hour plus expenses. Table 2.10–3 describes the fees per vessel type on an annual basis. For many of the vessel types, the annual user fee will represent a very small additional cost of doing business. For some categories of vessels, the fee may have a major impact. What follows is a discussion of the fee by type of vessel or examination. Where profit data was available it was used. In the absence of profit information for some vessel types, this analysis uses revenue per vessel per day. This allows comparisons in order to make some judgments about potential impacts on vessel owners and operators. It is assumed that if the cost of a user fee is less than one revenue day, the impact to that vessel is not significant.

This method of analysis is a "worst case" estimate. In economic terms demand would be described as perfectly elastic. That means that the market is perfectly competitive so that no vessel owner can raise the rental price, freight rate, or passenger fare on the vessel because the consumer could find a satisfactory substitute at the original price. If vessel owners are able to absorb the full cost of the user fee (from profits) then the fee will not have a significant impact.

The presence of perfect competition is rare. More common is the case where the vessel owner could pass along some of the cost of the fee. If the market for vessel services is less than perfectly competitive and the demand for vessel services is relatively inelastic, or is increasing, as in a booming market, the vessel owner could pass along a portion of the fee. If vessel owners are able to pass forward some or all the costs of the proposed user fees the impacts would be likewise reduced.

The market for vessels varies by type of vessel as well as external economic conditions. For example with the downturn experienced in the market price for oil in the 1980's the demand for offshore supply vessels and MODU's decreased. This decline forced these vessel owners to lower prices. In a down market or recession, the ability of vessel owner to absorb costs is considerably less than in a booming economy. With falling prices, the ability of the owner to pass cost increases to the consumer is also limited or eliminated. The impact of imposing fees, therefore, will vary with the industry in which the vessel operates as well as the state of the economy.

The first type of vessel to be discussed, Freight Barges, would have an annual user fee of $955 per year. The cost of this to industry would be $649,515 annually. These vessels are generally oceangoing deck barges that carry containers. According to an industry source, oceangoing freight barges range in size from 250–450 feet. With a tug, they rent for approximately $11,000–$15,000 a day. Without a tug they would rent for $1,000 a day. This $1,000 represents a figure that is higher than the annual user fee. The Coast Guard is convinced that the user fee for this industry will not represent an undue burden.

U.S. Flag Freight Ship. The cost of the user fee for freight ships would be $5,411 per year. The cost to the freight ship industry would be $2,261,879 annually. According to data provided by the U.S.

Maritime Administration for 1989, the total operating revenue of a U.S. flag breakbulk, LASH, or roll-on-roll-off vessel is $62,415 per day with a gross operating profit of $14,164. A U.S. flag container ship has revenue of $121,885 per day and a gross profit of $20,113 per day. The user fee represents significantly less than one day's profits of either of these two U.S. flag freight ships. It appears that even if U.S. flag freight ships must absorb this whole user fee it should cause them little problem.

Public freight ships would pay $4,245 per year. For purposes of this analysis the user fees for all public vessels should be considered a transfer payment from one government agency or department, e.g., the Maritime Administration, the Department of Defense, etc., to the U.S. Treasury and therefore does not have an impact on the general public or industry and will not be discussed in this analysis.

Industrial vessels would have a user fee of $2,751 per year. The cost to the entire industry would be $286,098 annually. A significant number of industrial vessels are dredging vessels. According to Michael Sickles of the National Association of Dredging Contractors the dredging industry is in the worst condition it has been in many years because the supply of dredging capacity is 100 million cubic yards while the demand is for only 30 million cubic yards. The price charged for a dredging vessel per day is $20,000 to $35,000. Although the industry is suffering, the cost of this user fee to this hard pressed industry should not have a significant impact on the industry as it represents only a small cost of doing business.

Liquefied Gas Tank Ships would have a user fee of $14,142 annually. The cost of this to the industry would be $169,705 annually. According to Lloyd's Shipping Economist March 1991 issue, a LPG tank ship of 24,000 cubic meters on a one month charter was $865,000–$895,000, a 52,000 cubic meter vessel $1,000,000 to $1,200,000 and a 75,000 cubic meter vessel $1,300,000–$1,395,000 respectively. For the smallest of these vessels that represents a day rate of over $28,800. The user fee represents just under ½ of the day rate for this type of vessel. It would appear that the proposed user fee does not represent an undue burden on these specialized ships.

Mobile offshore drilling units (MODUs) would face differential user fees depending on the type of unit. The Submersible and Self-elevating units will be assessed a fee of $4,698 a year, a Self Propelled Drillship $6,712 while a Semi-submersible Unit will be charged $8,054. The cost to the industry is $1,315,517. According to industry sources, the day rate of MODU's vary widely based on their size and complexity. The day rate for a U.S. flag MODU ranges from $12,000–$65,000 per day. The differential rates being charged by the Coast Guard reflect the differences in size and complexity of these vessels. This industry has in the last few years suffered from some over capacity which has depressed rates. Nevertheless, the Coast Guard's opinion is that these fees represent only a small amount compared to the cost of doing business in this industry.

Offshore Supply Vessels would face a user fee of $1,470 per year. The cost of this to industry would be $1,052,841 annually. According to a source in the offshore marine supply industry, the benchmark supply vessel of 180 feet costs approximately $2,500 a day to contract. The utilization rate in the industry in the Gulf of Mexico is relatively high at approximately 70–80%. There are approximately 360 domestic supply vessels. There are also 240 utility vessels and 170 crew boats which rent for $800–$1,200 a day. The 200 domestic lift boats have higher rates that are not as easily quoted as they are often rented for specific jobs. According to an offshore industry analyst, the return on revenues after taxes for supply vessels and crew and utility vessels were 15–20% last year and are around 10% for 1991. Although impact on the crew boats and utility boats will be more than on the 180 foot supply vessels, this industry is in relatively healthy condition and should be able to absorb these fees. The industry has shrunk over the last five years leaving those survivors in better economic shape.

Oceanographic Research vessels would have an annual fee of $4,199. The cost to this industry would be $71,389 annually.

More than half of these vessels are owned by the U.S. Government particularly the Navy. User fees on these vessels will therefore represent a transfer payment. Two of these vessels are owned by major oil companies with the rest owned by nonprofit foundations of other specialty companies. The Coast Guard does not consider that this user fee represents a significant burden to these highly specialized type of craft.

Nautical School Vessels would have a user fee of $7207 per year. The cost to the industry is $161,632 annually. Five of these vessels are owned by the U.S. Maritime Administration and one by the U.S. Navy and therefore involve a transfer payment from one U.S. agency to another. The rest are owned by colleges and foundations. These institutions may have to raise fees a modest amount to cover the cost of this user fee. The Coast Guard expects that these institutions will be able to pay these fees.

Passenger Ships (Subchapter H) and Small Passenger Vessels (Subchapter T) and Passenger Barges

This industry is a very difficult industry to characterize. The industry is made up of many small firms which own only one vessel. They could be described as small entities. Many of these vessels may sail only seasonally reflecting regional weather conditions. Other companies are large and have vessels that sail year around. The Coast Guard has tried to account for the differences in the industry by charging varying rates depending on the size of the vessel. The smallest vessel category, of less than 54 feet, would be faced with a fee of $820 a year, while a passenger ship of more than 450 feet has a fee of $14,650. (There are only four of these very large vessels, two of which are owned by the U.S. Navy). The cost to this entire industry would be $5,964,058 annually. The variance in the fees reflects the greater inspection requirements for the larger vessels. Because the vast majority of these companies are private sole proprietorships or closely held family businesses, financial data is not readily available. The National Association of Passenger Vessel Operators has been cooperative and has helped put the Coast Guard in touch with several passenger vessel operators. These operators describe an industry with net income of under 10% of revenue. In the case of some vessels, particularly seasonal ones, profits were close to zero.

The Coast Guard expects that the proposed user fees will not have a significant impact on this industry. Nevertheless, the Coast Guard requests information from passenger vessel owners and operators who believe they will be significantly impacted by this rulemaking. Information requested by the Coast Guard includes size and type of vessel, region of the country, and length of season. Economic theory would suggest that the most marginal firms in this industry which were making little to no net income (profits) might be forced to exist the industry.

U.S. Flag Tank Ships would face a user fee of $5,805. The cost of this rule to the tankship industry would be $1,602,226 annually. According to an industry source, the day rates of U.S. flag tankers range from $18,000 to $60,000 a day. Profit figures in the

industry were described as so volatile that it is very difficult to categorize them. The user fee should have little impact on this industry as they represent less than ⅓ of one day's revenue for even the lowest priced ships.

Public Tank Ships user fees are a transfer payment from one government agency to another.

Tank Barge inspection user fees are capped at $500 per year by statute. The cost of this to industry would be $2,044,000 annually. According to industry sources the present day rates for river tank barges are $400 per day for a 10,000 barrel barge, $800 a day for a 20,000 barrel barge and $1,000 for a 30,000 barrel vessel. For the smallest of these barges the user fee represents slightly more than one day's revenue. The Coast Guard's opinion is that the user fee will not have a significant impact on this industry, and will affect only marginal firms. The Coast Guard asks barge owners who believe they may be unduly impacted by the proposed fees to comment on the proposed fees.

Unclassified or other inspected vessels would be subject to a user fee of $1,032. The cost of this to the industry would be $78,225 annually. Many of these inspections were one of a kind inspections related to the Exxon Valdez oil spill. Several of these vessels were deck barges which carried dredging equipment. The Coast Guard's opinion is that this fee will not cause any undue burden for these vessels. However, because of the diversity of this group of vessels it is impossible to categorically state that no owner will be impacted by the imposition of user fees.

Foreign Passenger Vessels would be subject to control verification user fee of $1047. This fee is a pay as you go fee. Since many of these vessels are inspected quarterly, the cost per vessel may be $4188 annually. The cruise industry has experienced tremendous growth during the 1980's of around 10% annually. Growth during the nineties is expected to be more modest. The industry is dominated by four carriers which control 61% of the business according to a member of the cruise industry press. The industry has been consolidating recently with mergers and exists from the industry. This trend should continue in the 1990's. There are two distinct sectors in the cruise industry, the upscale smaller ships of 100–200 passengers and the large cruise ships of 1,000–2,000+ passengers. Net revenue per passenger is $300 per passenger day for the luxury small ships and $100 per passenger day for the large ships. The user fee would be a small cost of doing business for this industry. The total cost to the industry is expected to be $464,921.

Tank Vessel Examination (TVE) and Certificate of Compliance (COC) for foreign flag tank ships would be $1102 per year. Tank ship trip day charter rates according to Lloyd's Shipping Economist March 1991 issue were from $13,000 to $28,000. The user fee represents a minimal cost of these ships. The total cost to the industry is expected to be $1,343,306.

Overseas Inspection Fees for inspections on U.S. vessels in foreign countries in an additional $4586. For the oceangoing U.S. vessels discussed earlier, this represents substantially below one revenue day for these vessels. The total cost to the industry could be as much as $3.5 million.

Foreign MODU's should have no problem in paying the same user fee as U.S. vessels, for those complying with U.S. design and equipment standards, or the user fee of $1831 annually for those complying with the requirements of the International Maritime Organization or of the documenting nation. The revenues of these vessels should be in the same general amount as those of U.S. flag MODUs, and the impact will be approximately the same. The overall cost to the foreign segment of the industry is estimated to be $35,000.

Conclusion

In conclusion the Coast Guard does not expect the proposed user fees to have an undue impact on industry, the general public, productivity, innovation, international trade, inflation, employment or any regions or on state and local governments. It is the Coast Guard's opinion that this fee will not have a significant impact on a substantial number of small entities. However, the Coast Guard awaits further information from the domestic small passenger vessel and tank barge industries on possible impacts.

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federal register

Tuesday
December 24, 1991

Part VIII

The President

Legislation

Federal Register
Vol. 56, No. 247
Tuesday, December 24, 1991

Presidential Documents

Title 3—

The President

Proclamation 6396 of December 20, 1991

National Law Enforcement Training Week, 1992

By the President of the United States of America

A Proclamation

High-quality training is an essential component of effective law enforcement. The dedicated men and women who serve in this field have sworn to uphold the constitutional rights of individuals while promoting and defending the public safety. Meeting that challenge requires that every officer—from the rookie on the street to the most experienced chief or investigator—be equipped with certain knowledge and skills.

Today law enforcement training is as rigorous and as wide-ranging in scope as the day-to-day demands of an officer's job. First, every man and woman behind the badge must have knowledge of the law itself, including the rules of proper conduct and procedure. Because their work places them on the front lines in the war against drugs and crime, law enforcement officers also devote many hours of study and practice to self-defense techniques and to the safe use of firearms. Basic law enforcement training also includes physical conditioning, as well as lessons and exercises in the administration of first aid. Whether they are called to the scene of an accident or to the site of a violent domestic dispute, law enforcement officers know that lives depend on their preparedness and skill.

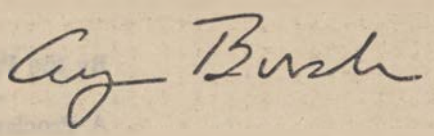
While the fundamentals have remained the same, recent advances in science and technology have changed many aspects of law enforcement and law enforcement training. To fight back against increasingly sophisticated crimes, police officers and other law enforcement agents are employing increasingly sophisticated tools and methods, from computers and toxicology to genetic "fingerprinting" and psychological profiling. Thus, those individuals who provide law enforcement training—including continuing education for veteran personnel—are part of a large, multidisciplinary team of professionals.

This week, as we gratefully salute all those who conduct and participate in law enforcement training, we also acknowledge the many rewarding career opportunities that it offers through its related disciplines. Young Americans who aspire to serve in our Nation's law enforcement and criminal justice system are encouraged to learn more about them.

To heighten public awareness of the importance of law enforcement training and its related fields, the Congress, by Public Law 102–206, has designated the week of January 5 through January 11, 1992, as "National Law Enforcement Training Week" and has authorized and requested the President to issue a proclamation in observance of this week.

NOW, THEREFORE, I, GEORGE BUSH, President of the United States of America, do hereby proclaim the week beginning January 5, 1992, as National Law Enforcement Training Week. I invite all Americans to observe this week with appropriate programs and activities.

IN WITNESS WHEREOF, I have hereunto set my hand this twentieth day of December, in the year of our Lord nineteen hundred and ninety-one, and of the Independence of the United States of America the two hundred and sixteenth.



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Presidential Documents

Proclamation 6397 of December 20, 1991

National Sanctity of Human Life Day, 1992

By the President of the United States of America

A Proclamation

Throughout our Nation's history, Americans have treasured these timeless words from our Declaration of Independence: "We hold these truths to be self-evident, that all men are created equal, that they are endowed by their Creator with certain unalienable Rights, that among these are Life, Liberty and the pursuit of Happiness." These stirring words summarize the fundamental moral vision of the United States, a vision that affirms the inestimable dignity and worth of every human being, each of whom is made in the image of God. They were not words uttered lightly. Signers of the Declaration pledged to uphold them with their lives, their fortunes, and their sacred honor. On this occasion, we reflect on the first and most fundamental right enumerated by our Nation's founders: the right to life.

Thomas Jefferson noted that "the God who gave us life gave us liberty at the same time," and much of his writing reflects his belief that "the care of human life and happiness, and not their destruction, is the first and only legitimate object of good government." Thus, respect for the sanctity of human life is deeply rooted in the American tradition. Today we Americans are rightfully proud of our physicians and scientists, who have helped lead the way in the fight against disability and disease; proud of the thousands of American service members and volunteers who have responded to calls for help around the world; and grateful to the many fire fighters and law enforcement officers who work to protect the public safety. These are just a few of the millions of Americans who demonstrate, through their daily labors, our Nation's traditional reverence for human life.

While the United States boasts a long and honorable tradition of respect for human life and the rights of individuals, one key issue related to the sanctity of life is a divisive one in America today: the issue of abortion.

Fewer than 20 years after the 1973 Supreme Court ruling in *Roe* v. *Wade,* the prevalence of abortion on demand in the United States stands in stark contrast to our Nation's most deeply held values and beliefs. While sincere persons may disagree, my position is that the lives of both mother and child must be cherished and protected.

Advances in science and technology continue to provide evidence that the child developing in the mother's womb is a distinct, living individual who bears all the basic attributes of human personality. How terribly ironic that an unborn child in one medical facility may be carefully treated as a patient while at another facility—perhaps just a few blocks away—another unborn child will bcome the innocent victim of abortion.

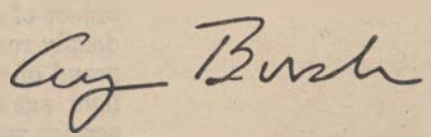
Women and men who operate crisis pregnancy centers across the country recognize the fear and desperation that compel some women to consider abortion. Yet they also know that, in a Nation as prosperous as ours, where people are known for their open hearts and their unfailing generosity, this tragic choice is unnecessary.

On this occasion, we acknowledge the selflessness and compassion of all those volunteers who offer emotional, physical, and financial support to women facing crisis pregnancies. We also salute those courageous women who choose life for their unborn children and thank the dedicated counselors, social workers, and other professionals who, where needed, offer assistance in adoption. As a Nation, we must continue to dismantle legal, financial, and attitudinal barriers to adoption, to make adopting easier for families who want children and who will give them loving homes—particularly children with special needs.

On this ninth National Sanctity of Human Life Day, let us renew our determination to ensure that all, born and unborn, receive the protection and care they deserve. Together, let us choose life, so that America might always be known as a good and giving Nation, a nation where the stranger is welcomed and the needy are served with dignity and kindness. That is the sure and noble path chosen at our Nation's founding and the path to which we must always return.

NOW, THEREFORE, I, GEORGE BUSH, President of the United States of America, by virtue of the authority vested in me by the Constitution and laws of the United States, do hereby proclaim Sunday, January 19, 1992, as National Sanctity of Human Life Day. I call on all Americans to reflect on the sanctity of human life in all its stages and to gather in homes and places of worship to give thanks for the gift of life and to reaffirm our commitment to respect the life and dignity of every human being.

IN WITNESS WHEREOF, I have hereunto set my hand this twentieth day of December, in the year of our Lord nineteen hundred and ninety-one, and of the Independence of the United States of America the two hundred and sixteenth.



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H.R. 2950/Pub. L. 102-240

Intermodal Surface Transportation Efficiency Act of 1991. (Dec. 18, 1991; 105 Stat. 1914; 294 pages) Price: $9.50

H.R. 1776/Pub. L. 102-241

Coast Guard Authorization Act of 1991. (Dec. 19, 1991; 105 Stat. 2208; 28 pages) Price: $1.00

S. 543/Pub. L. 102-242

Federal Deposit Insurance Corporation Improvement Act of 1991. (Dec. 19, 1991; 105 Stat. 2236; 158 pages) Price: $4.50

Last List December 20, 1991